

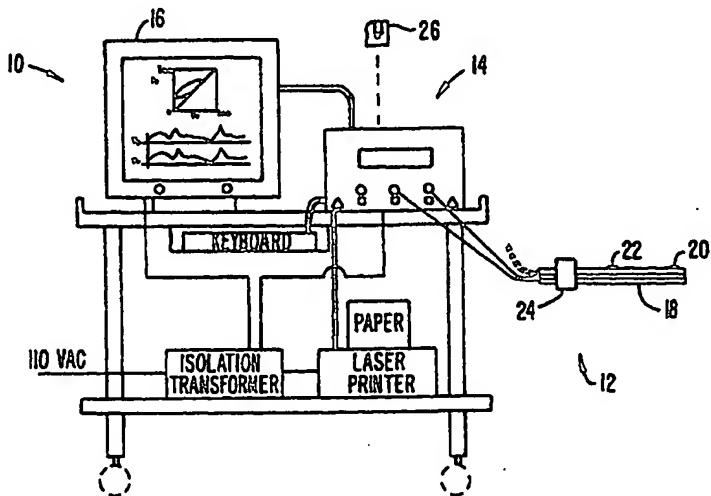
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(54) Title: URINARY INCONTINENCE DIAGNOSTIC SYSTEM



(57) Abstract

This invention is devices, systems, and methods for diagnosing and/or treating urinary incontinence that can accurately, reliably monitor both a vesicle pressure (Pv) and a maximum urethral pressure (Pm) of a patient during an abdominal pressure pulse so as to determine relationships between these pressures. Alignment between the location of maximum urethral pressure (30) and a pressure sensor (20, 22) of a catheter (18) can be maintained using an anchoring structure (24) having a surface which engages a tissue surface along the bladder neck, urethra (UR), or external meatus (EM), which move with the urethra (U) during abdominal pressure pulses. A pressure gram is generated graphically showing an increase in urethral pressure relative to an increase in vesicle pressure, and is often displayed in real time to a system operator adjacent the patient. Quantitative and/or qualitative diagnostic outputs allow selective remodeling of the patient's support structure so that the incontinence is inhibited.

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URINARY INCONTINENCE DIAGNOSTIC SYSTEM

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TECHNICAL FIELD

The present invention generally relates to devices, system, and methods for diagnosing and/or treating urinary incontinence. In an exemplary embodiment, the invention provides catheter-based pressure sensing systems for diagnosing female urinary incontinence, and in particular, provides systems for determining the relationship between urethral pressure and vesicle pressure in response to changes in abdominal pressure. Preferred aspects of the present invention relate to urethral catheter holder mechanisms.

BACKGROUND OF THE INVENTION

Urinary incontinence arises in both men and women with varying degrees of severity, and from different causes. In men, the condition most frequently occurs as a result of prostatectomies which result in mechanical damage to the urethral sphincter. In women, the condition typically arises after pregnancy when musculoskeletal damage has occurred as a result of inelastic stretching of the structures which support the genitourinary tract. Specifically, pregnancy can result in inelastic stretching of the pelvic floor, the external sphincter, and the tissue structures which support the bladder and

bladder neck region. In each of these cases, urinary leakage typically occurs when a patient's abdominal pressure increases as a result of stress, e.g., coughing, sneezing, laughing, exercise, or the like.

Treatment of urinary incontinence can take a variety of forms. Most simply, the patient can wear absorptive devices or clothing, which is often sufficient for minor leakage events. Alternatively or additionally, patients may undertake exercises intended to strengthen the muscles in the pelvic region, or may attempt a behavior modification intended to reduce the incidence of urinary leakage.

In cases where such non-interventional approaches are inadequate or unacceptable, the patient may undergo surgery to correct the problem. A wide variety of procedures have been developed to correct urinary incontinence in women. Several of these procedures are specifically intended to support the bladder neck region. For example, sutures, straps or other artificial structures are often looped around the bladder neck and affixed to the pelvis, the endopelvic fascia, the ligaments which support the bladder, or the like. Other procedures involve surgical injections of bulking agents, inflatable balloons, or other elements to mechanically support the bladder neck.

In work related to the present invention, it has recently been proposed to treat incontinence by directing energy to a tissue structure comprising or supporting the patient's urethra, bladder neck, or bladder. The energy can contract collagenous structures such as fascia, tendons, or the like, increasing the structural support of these natural support tissues. As described in PCT Application Serial Nos. 98/16754 and 97/20191, the full disclosures of which are incorporated herein by reference, the energy may be transmitted through an intermediate tissue, or by accessing the collagenous tissue surface in a minimally invasive manner.

Researchers have studied female urinary incontinence by evaluating the relationship between a patient's urethral pressure and her vesicle (i.e.: bladder) pressure. In an article by Kim et al., *The Vesico-Urethral Pressuregram Analysis of Urethral Function Under Stress*, Journal of Biomechanics, Vol. 30, page 19 (1997), proposed a method for analyzing the interaction between the vesicle pressure and urethral pressure to assess urinary stress incontinence. Both urethral pressure and vesicle pressure will change in response to changes in abdominal pressure. However, the urethral and vesicle pressures may change at different rates as the abdominal pressure changes. Incontinence may occur when the vesicle pressure exceeds the urethral pressure. Hence, incontinence

can be studied by producing a pressuregram showing the relationship between the urethral pressure and the vesicle pressure of the patient during abdominal pressure pulses.

A patient's vesicle and urethral pressures can be measured by introducing a catheter into the urethra and positioning pressure sensors of the catheter at the desired measurement sites in the urethra and/or bladder. The measurements of the patient's vesicle and urethral pressures are preferably taken simultaneously during changes in abdominal pressures.

Unfortunately, simultaneous pressure measurements can be difficult to obtain using presently available pressure-sensing catheters. Hence, existing systems are not well suited for diagnosing urinary incontinence of a particular patient. Similarly, while the recently proposed tissue contraction therapies offer great promise for treatment of urinary stress incontinence, proper treatment to enhance elongated or weak support structures of a particular patient could benefit significantly from improved techniques for diagnosing urinary incontinence.

In light of the above, it would be desirable to provide improved devices, systems, and methods for diagnosing and/or treating urinary incontinence.

SUMMARY OF THE INVENTION

The present invention generally provides improved devices, systems, and methods for diagnosing and/or treating urinary incontinence. The invention provides pressure-sensing catheter systems which can accurately and reliably monitor both a vesicle pressure and a maximum urethral pressure of a patient during an abdominal pressure pulse so as to determine relationships between these pressures. Work in connection with the invention has shown that diagnostic urethral pressure measurements during a pressure pulse are sensitive to loss of alignment between the pressure sensor and the target pressure location. Advantageously, alignment between, for example, the location of maximum urethral pressure and a pressure sensor of a catheter can be maintained using an anchoring structure having a surface which engages a tissue surface along the bladder neck, urethra, or external meatus (the tissue structure adjacent the urethral opening). These tissues generally move with the urethra during abdominal pressure pulses, so that the anchoring structure will often move the pressure sensor when an abdominal pressure pulse is induced. The invention allows a reliable, accurate pressuregram to be generated, the pressuregram graphically showing an increase in urethral pressure relative to an increase in vesicle pressure. This pressuregram will

ideally be displayed in real time to a system operator adjacent the patient, and may provide a quantitative and/or qualitative diagnostic output allowing selective remodeling of the patient's support structure so that the incontinence is inhibited.

In a first aspect, the invention provides an apparatus for evaluating urinary incontinence of a patient. The patient has a urethra extending from a bladder to a urethral opening, with a maximum urethral pressure disposed between the bladder and opening. The system comprises a pressure-sensing system including an elongate body having a proximal end and a distal end. A vesicle pressure sensor is disposed adjacent the distal end for measuring fluid pressure within the bladder. At least one urethral pressure sensor is disposed proximally of the vesicle pressure sensor for measuring urethral pressure. An anchoring structure is disposed along the elongate body. The anchoring structure is adapted to engage a tissue surface adjacent the urethra so as to maintain alignment between the urethral pressure sensor and the maximum urethral pressure when a pressure pulse moves the urethra. A processor is coupled to the pressure-sensing system. The processor calculates a relationship between the urethral pressure and the vesicle pressure.

Typically, the calculated relationship will comprise a pressuregram which is shown on a display in real time to a system operator disposed adjacent the patient. The pressuregram will typically include a slope defined by an increase of the measured vesicle pressure relative to an increase of the measured urethral pressure. Such pressuregram may be calculated from a plurality of pressure pulses, and will typically be independent of time. The pressuregram may be displayed in a variety of formats, including plotting simultaneous pressure data pairs taken simultaneously in the urethra and the bladder, with vesicular pressure along a horizontal axis and urethral pressure along a vertical axis or *vice-versa*.

The anchoring structure will often comprise a radially expandable structure, the expandable structure preferably having at least one channel allowing free transmission of urine through the urethra when expanded. Suitable expandable structures include balloons having multiple lobes defining the channel therebetween. The expandable structure may expand within the urethral passage to engage the surrounding tissues, or may be inserted and expanded beyond the urethra so that a proximally oriented surface of the expandable structure engages the bladder. In many embodiments, a distally oriented surface will be positionable along the elongate body to engage an external meatus so as to substantially affix the urethral pressure sensor relative to the maximum urethral pressure location.

The anchoring structure may comprise at least one vacuum port disposed along the elongate body and oriented to engage a tissue along the urethra. When a vacuum is applied to the vacuum port, the vacuum port can safely secure the urethral pressure sensor at the desired position within the urethra. In some embodiments, a 5 plurality of urethral pressure sensors may be distributed axially so as to reduce sensitivity of the pressure sensor system to movement relative to the surrounding urethra.

The present invention also provides a urethral catheter holder which is adapted to support a pressure-sensing catheter such that the catheter can be positioned along the patient's urethra. The holder can generally maintain alignment with a 10 maximum urethral pressure by allowing the catheter to move in response to urethral movement such that a pressure-sensing transducer disposed on the catheter does not move relative to the urethra when the patient coughs.

In a preferred aspect of the present invention, the urethral catheter holder comprises a supporting base, which is adapted to register against the labia of the patient; a 15 suspension housing mounted to the supporting base; a catheter securement device, (which is adapted to move within the suspension housing when the patient coughs such that the catheter moves with the urethra); and a biasing device. In preferred aspects, the catheter securement device comprises a catheter guide which is adapted to contact against the external meatus of the patient's urethra. The biasing device operates to provide a pre- 20 loading force on the catheter guide, thereby holding the catheter guide against the external meatus of the patient's urethra such that the catheter securement device moves with the movement of the urethra. Additionally, the biasing device operates to push the catheter securement device against the supporting base, thereby minimizing unwanted motion of the catheter securement device within the suspension housing.

25 The catheter securement device is adapted to support the catheter in a manner such that the catheter moves in response to movement of the urethra, with the catheter remaining in generally the same position relative to the surrounding urethra when the patient coughs. In a preferred aspect, the catheter securement device comprises a torroidal balloon, a generally ring-shaped balloon support mount surrounding the 30 torroidal balloon and a pneumatic or hydraulic pressure tube for inflating or deflating the torroidal balloon. The catheter passes longitudinally through the catheter holder and is received through the orifice defined by the torroidal balloon. Inflation of the torroidal balloon will cause it to expand radially inwardly such that its central orifice contracts, thereby gently pushing against the sides of the catheter.

In other preferred aspects of the invention, the catheter securement device comprises a mechanical clamp which is mounted to move longitudinally within the suspension housing.

Optionally, the present urethral catheter holder may also comprise a pair of leg straps, which can be wrapped around the patient's thighs, (or a stretchable undergarment with leg straps attachable thereto), such that the supporting base of the catheter holder can be held at a generally fixed position against the labia of the patient. An advantage of such leg straps is that pressure measurements can then be taken easily with the patient in different positions, including supine and sitting. An additional 5 advantage of the present system is that it allows hands-free operation for the clinician.

In another aspect, the invention provides a data system for use with a mechanism for diagnosing urinary incontinence of a patient. The mechanism produces a pressuregram indicating a pressuregram slope defined by a change of urethral pressure of the patient relative to a change of vesicle pressure of the patient. The vesicle and urethral pressures are measured with a catheter system having a proximal end and a distal end. 15 The data system comprises a processor coupled to the catheter for receiving a vesicle pressure signal and urethral pressure signal. The processor generates a pressuregram dataset in real time. At least in part from the vesicle and urethral pressure signals. A display is coupled to the processor so as to generate a real time image of the pressuregram 20 from the pressuregram dataset. The display is visible from adjacent the proximal end of the catheter.

Generally, a soft tissue of the patient moves with the urethra during a pelvic pressure pulse. Suitable pressure pulses can be induced by having the patient cough, by having the patient perform the Valsalva maneuver, by pushing manually or 25 with an impulse device against the abdomen, or the like. To accommodate the resulting tissue movement, the system will often include a catheter positioning surface attached to the catheter. The catheter positioning surface will be adapted to engage the soft tissue so as to inhibit movement of the catheter within the urethra. In some embodiments, the positioning surface may be insertable along at least a portion of the urethra. Such 30 positioning surface include high friction outer catheter surfaces, surfaces surrounding vacuum ports, atraumatic balloons, and the like. Optionally, some mechanism for facilitating insertion and removal of the catheter may be provided, such as a low friction interface sheath, or the like.

Alternative embodiments may include positioning surfaces which are larger in cross-section than the catheter so as to engage a soft tissue beyond the urethra, such as an external meatus, bladder, or the like, with such large positioning surfaces often being adjustably affixable along an axis of the catheter to facilitate positioning of the 5 urethral pressure sensor at the point of maximum urethral pressure. In such embodiments, a biasing mechanism will often support the positioning surface against the external meatus, the support often reacting against a reaction support such as leg straps, a garment, or the like. The biasing mechanism will preferably allow at least about 2 cm of movement of the external meatus and catheter without altering the alignment of the 10 urethral pressure sensor.

The processor will preferably selectively display one or more pressure pulses, and will ideally be selectively capable of refreshing the display between pressure pulses. An exemplary processor extrapolates an equilibrium pressure (above which the vesicle pressure exceeds the urethral pressure) using a curve approximation of the 15 pressuregram.

In yet another aspect, the invention provides a system for treatment of urinary stress incontinence of a patient. The patient has a tissue comprising or supporting the urethra, the bladder neck, or the bladder. The system comprises a diagnostic system including a urethral pressure sensor, a bladder pressure sensor, and a processor coupled to 20 the sensors. The processor generates an output indicating a desired remodeling of the tissue of the patient. A probe has an energy-transmitting element that controllably delivers energy to the tissue so as to effect the desire remodeling such that incontinence is inhibited.

In some embodiments, the probe may be used to controllably deliver the 25 energy in response to the output of the processor. Optionally, the processor may be coupled to the probe and may provide an energy signal to the probe so as to control the delivered energy.

In another method aspect, the invention provides a method for treating urinary stress incontinence of a patient. The method comprises sensing a bladder pressure 30 and a urethral pressure. A desired remodeling of a tissue comprising or supporting a urethra, a bladder neck, and/or a bladder of the patient is determined from the bladder pressure and the urethral pressure. The desired remodeling of the tissue is effected so that incontinence is inhibited.

Typically, a pressure pulse will be generated during the sensing step. The pressure pulse may, in some embodiments, be generated after effecting partial remodeling of the tissue for use as feedback during the remodeling step.

- In yet another method aspect, the invention provides a method for
- 5 treatment of urinary stress incontinence of a patient. A pressuregram of the patient indicates a urethral pressure of the patient which differs from a vesicle pressure of the patient by a continence margin. The pressuregram has a pressuregram slope defined as a change of the vesicle pressure relative to a change of the urethral pressure. The pressuregram slope is such that the vesicle pressure will exceed the urethral pressure of
- 10 the patient above an equilibrium pressure. The method comprises determining a desired change in a support tissue comprising or supporting the urethra based at least in part on the equilibrium pressure, the continence margin, and/or the pressuregram slope. The support tissue is remodeled per the desired change.

The remodeling step may comprise directing energy into the support tissue

15 so as to contract the support tissue. Often times, a plurality of pressuregrams will be taken with the patient in different positions, such as standing, sitting, supine, and the like, for determining the desired change.

In yet another aspect, the invention provides a system for evaluating

urinary incontinence. The system comprises a body having a proximal end, a distal end,

20 and a cross-section suitable for insertion into a urethra. A pressure sensor is disposed along the body for measuring urethral pressure, and a position sensing system or means is couplable to the body to measure an axial position of the pressure sensor within the urethra.

BRIEF DESCRIPTION OF THE DRAWINGS

25 Fig. 1 is a schematic illustration of a system for diagnosing urinary stress incontinence according to the principles of the present invention.

Fig. 2 shows a cut-away view of tissues supporting the bladder, bladder neck, and urethra.

Figs. 3A and B schematically show target pressure measurement locations

30 along the urethra, and illustrate the sensitivity of pressuregram measurements to loss of alignment with the location of maximum urethral pressure.

Fig. 4 schematically illustrates an exemplary pressure measurement system for use in the diagnostic system of Fig. 1, the pressure measurement system including a pressure measurement catheter and an anchoring structure.

5 Fig. 5 schematically illustrates a pressure measurement catheter for use in the pressure measurement system of Fig. 4.

Fig. 6 is an exploded view of an alternative anchoring structure for use in the pressure measurement system of Fig. 4, here in the form of a urethral catheter holder.

Fig. 6A is a top view of the urethral catheter holder of Fig. 6.

Fig. 6B is a front view of the urethral catheter holder of Fig. 6.

10 Fig. 6C is a right-side view of the urethral catheter holder of Fig. 6.

Fig. 6D is a rear view of the urethral catheter holder of Fig. 6.

Fig. 6E is a sectional plan view of the urethral catheter holder taken along line 6E-6E in Fig. 6D.

15 Fig. 6F is a sectional elevation view of the urethral catheter holder taken along line 6F-6F in Fig. 6D.

Fig. 7 is a view corresponding to Fig. 6F, but with a catheter received through the holder.

Fig. 8 shows positioning of the catheter holder by way of leg straps.

20 Fig. 9 shows positioning of the catheter holder by way of leg straps and a stretchable undergarment.

Fig. 10 is a schematic view of a system for evaluating female urinary incontinence incorporating the present urethral catheter holder.

25 Fig. 11 is an illustration of a pressuregram showing the relationship between the vesicle pressure and the urethral pressure for two different patients at different abdominal pressures.

Fig. 12 shows a mechanical clamp for use in the catheter securement device.

Fig. 13 shows a perspective view of an alternate embodiment of the present invention, comprising the mechanical clamp of Fig. 12.

30 Fig. 14 illustrates an alternative anchoring surface for engaging a tissue adjacent the urethral opening and for allowing the system operator to visually monitor for leakage.

Figs. 15A and 15B schematically illustrate a pressure measurement catheter anchored within the urethra by a multiple-lobed balloon, the balloon defining

axial passages when inflated within a urethra so as to decrease pressure effects of the measurement system.

Fig. 16 illustrates an alternative pressure measurement catheter which can be anchored within the urethra by a series of vacuum ports on a surface of the catheter.

5 Fig. 17 illustrates an alternative pressure measurement catheter having a plurality of independent axially separated urethral pressure sensors so as to decrease sensitivity of the pressure sensor system to movement between the catheter and maximum urethral pressure.

Fig. 18 is a portion of a pressuregram dataset measured using the pressure
10 measurement system.

Fig. 19 is a pressuregram of a continent woman taken with minimal relative movement between the measurement catheter and the urethra.

Figs. 20A and 20B are pressuregrams taken with significant relative movement between the measurement catheter and the urethra.

15 Fig. 21 schematically illustrates a screen displaying a real-time pressuregram to a pressuregram system operator.

Fig. 22 is a flow chart showing exemplary method steps for diagnosing and/or treating urinary incontinence.

20 Figs. 23A-C schematically illustrate devices and methods for measuring a urethral pressure profile as illustrated in Fig. 3B, in which the profile accuracy can be independent of the rate at which the pressure sensor moves.

Figs. 24A-C schematically illustrate methods for inhibiting incontinence by remodeling collagenous support tissues by transmitting energy to the tissues.

25 Fig. 25 illustrates an integrated diagnostic/treatment system for urinary incontinence.

Figs. 26A-C illustrate probes for treating incontinence and methods for their use.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Referring first to Fig. 1, an exemplary diagnostic system 10 for evaluating
30 urinary incontinence generally includes a pressure measurement system 12, a processor 14, and a display 16. Pressure measurement system 12 includes a pressure measurement catheter 18 including a distal vesicle pressure sensor 20 and a more proximal urethral pressure sensor 22. An anchoring structure 24 maintains alignment between urethral

pressure sensor 22 and a target location of the urethra by engaging a soft tissue adjacent the urethra, as will be described in detail below.

Processor 14 may include an embedded personal computer (PC) running programming embodying the methods of the present invention in a tangible machine readable medium. A wide variety of tangible media are encompassed by the present invention, such as a floppy disk 26, a hard disk, an optical disk, a non-volatile memory, or the like. In some embodiments, the programming may be downloaded via a data transmission system such as an Ethernet, an internet or intranet, or the like. Processor 14 will preferably run the programming on a Windows™ operating system, and may 10 optionally use commercially available data manipulation programs such as Excel™, or the like. The processor typically comprises a commercially available PC such as an IBM™ clone, Pentium™, or the like. Display 16 will generally comprise a standard commercially available VGA monitor, or the like.

Some of the tissue structures which support the urethra are illustrated in 15 Fig. 2. This drawing shows the pelvic support tissues which generally maintain the position of much of the genitourinary tract, and particularly the position of urinary bladder B. Of particular importance for the method of the present invention, endopelvic fascia (EF) may define a hammock-like structure which extends laterally between the left and right arcus tendinous fascia pelvis (ATFP). These later structures may extend 20 substantially between the anterior and posterior portions of the pelvis, so that the endopelvic fascia (EF) largely defines the pelvic floor.

The fascial tissue of the pelvic floor may comprise tissues referred to under different names by surgeons of different disciplines, and possibly even by different practitioners within a specialty. In fact, some surgeons may assign the collagenous 25 support structure referred to herein as the endopelvic fascia one name when viewed from a superior approach, and a different name when viewed from an inferior approach. Some or all of this support structure may comprise two collagenous layers with a thin muscular layer therebetween, or may comprise a single collagenous layer. In general terms, the diagnostic and treatment techniques of the present invention may be directed toward any 30 of the collagenous portions of the support structures for the urethra, bladder neck, and bladder. Hence, the tissues of interest may include and/or be referred to as endopelvic fascia, arcus tendinous fascia pelvis, urethropelvic ligaments, periurethral fascia, levator

fascia, vesicopelvic fascia, transversalis fascia, and/or vesicle fascia, as well as other collagenous support structures.

In women with urinary stress incontinence due to bladder neck hypermobility, the bladder has typically dropped between about 1.0 cm and 1.5 cm (or 5 more) below its nominal position. This condition is typically due to weakening and/or stretching of the pelvic support tissues, including the endopelvic fascia, the arcus tendinous fascia pelvis, and the surrounding ligaments and muscles, often as a result of bearing children. When a woman with urinary stress incontinence sneezes, coughs, laughs, or exercises, the abdominal pressure often increases momentarily. Such pressure 10 pulses force the bladder to descend still farther, shortening or misaligning the urethra UR and momentarily opening the urinary sphincter. The tissues adjacent the urethral opening are generally referred to as the external meatus EM.

Locations along urethra U targeted for pressure measurement can be understood with reference to Figs. 3A and B. In general, a patient remains continent 15 when a maximum urethral pressure P_m along urethra U is larger than a vesicle pressure P_v . It should be noted that when describing the structures of the urethra and adjacent tissues, the portions adjacent bladder B are considered proximal, while the portions adjacent external meatus EM are considered distal. With this in mind, pressure within bladder B is substantially uniform, while the urethral pressure rises distally between a 20 urethro-vesicular junction U-VJ and an adjacent proximal urethra PU. Similarly, pressure will rise proximally from the external meatus EM to the adjacent distal urethra DU. A location 30 of the maximum urethral pressure P_m will be between these ends. While maximum pressure location 30 is commonly referred to as the mid-urethra, and maximum pressure P_m is commonly referred to as the mid-urethral pressure, it should be understood 25 that this location need not necessarily be disposed at the geometrical midpoint of the urethral passage. It should also be understood that the corresponding catheter structures and their movement within the urethra will be described with reference to a distal orientation extending from the external meatus inward toward the bladder.

As schematically illustrated in Fig. 3B, the maximum urethral pressure P_m 30 is quite limited in length along the axis of urethra U, the enhanced pressure often having a width in a range from about 3 to about 5 mm. Consequently, any significant movement of a pressure sensor from the maximum pressure location 30 could lead to substantial measurement errors. As urethral pressure measurements will preferably be taken during abdominal pressure pulses, and as such pressure pulses can cause the soft tissues along

urethra U to move significantly, anchoring structure 24 can significantly enhance measurement accuracy and reliability by inhibiting movement between the pressure sensor and the target location 30.

An exemplary pressure sensing system 12 can be seen more clearly in Fig. 5 4. Pressure sensing catheter 18 comprises an elongate body 32 with a proximal end 34 and a distal end 36. Vesicular pressure sensor 20 is disposed adjacent distal end 36, and may optionally comprise a port opening to a fluid lumen in communication with a pressure transducer, which may be mounted along catheter body 32, adjacent proximal end 34, or even be incorporated into processor 14. Alternative pressure sensors which 10 may be suitable include solid state piezo-resistive transducers mounted at the sensor port location, optical pressure sensors, and the like. Urethral pressure sensor 22 may similarly comprise any of a variety of alternative sensor structures, typically comprising a structure similar to that of the vesicle pressure sensor. A urethral sensor coupler 38 and a vesicular sensor coupler 40 detachably couple the pressure sensors to processor 14, using fluid, 15 optical, or electrical signals to transmits pressure information to the processor as appropriate for the sensor structures.

Catheter 18 may comprise a specialized multi-lumen structure having an outer diameter in a range from about 4 Fr to about 14 Fr fabricated from a suitable polymer. Typical total lengths for urethra U will be about 3-5 cm for women, and the 20 length between urethral pressure sensor 22 and both vesicle pressure sensor 22 and proximal end 34 will typically be at least 5 cm to allow simultaneous bladder and urethral pressure measurements throughout the urethra. Catheter 18 may comprise or be modified from an off-the-shelf dual pressure sensing catheter such as those sold by Life Tech under the model name Triple Lumen Urinary Catheter™, by GAEYTEC under the name Dual 25 Transducer Micro-Tip Catheter™, or the like. Suitable fluid transducers for use with fluid coupling catheters include the disposable medical pressure transducers sold by UTAH MEDICAL under the name Delta I™ or Deltran I™.

Urethral pressure sensor 22 of catheter 18 may be held in alignment with an anchoring sheath 24a. Sheath 24a has a lumen which extends from a proximal clamp 30 42 to a distal port 44, the lumen slidingly receiving catheter 18. Clamp 42 can releasably affix catheter 18 to sheath 24a. An elongate opening 44 through the wall of sheath 24a exposes urethral pressure sensor 22 throughout a range of catheter positions. Sheath 24a has a length less than that of catheter 18, and will typically have an inner diameter in a

range from about 4 Fr to about 14 Fr so as to receive the catheter therein. Sheath 24a will typically comprise a polymer, often comprising a multi lumen high strength biocompatible polymer structure commercially available from a variety of sources.

Anchoring sheath 24a includes a distal balloon 48 which is in fluid communication with a balloon inflation coupler 50 via a balloon inflation lumen of the sheath. Balloon 48 may optionally have an expanded diameter larger than that of the urethra, the balloon generally being rounded and conforming to the shape of the bladder neck so that a proximal surface of the balloon engages the soft tissue of the bladder adjacent the urethra. Alternative balloon designs may have multiple lobes so as to define channels between the balloon surface and the engaged tissue, as will be described below. Such channels may be defined by two-sided balloons or balloons having a winged configuration, and help to avoid impeding of the natural flow of urine during urodynamic exams.

Balloon 48 is inserted in a low profile configuration through urethra U, inflated within the bladder via balloon port 50, and engages the bladder neck to inhibit proximal movement of the sheath. A simple washer 50 is slidable over sheath 24a by hand, and frictionally resists movement when in position. Washer 50 has a distally oriented surface which may be conical (as shown in Fig. 4) planer, or the like, and will preferably comprise a soft, compliant polymer such as a rubber or the like to reduce patient discomfort. Once sheath 24a is positioned with balloon 48 engaged against the bladder neck, washer 50 can be slid against the external meatus, thereby clamping the urethra between the proximally oriented surface of the balloon and the distally oriented surface of the washer, effectively inhibiting movement of the sheath relative to the urethra.

As catheter 18 can slide within the lumen of sheath 24a while urethral sensor 22 is exposed through opening 46, the pressure sensor can be accurately positioned at target location 30 by moving the catheter axially while viewing a display indicating the pressure at the urethral sensor in real time. Once the displayed pressure is at its maximum, catheter 18 can be axially affixed to sheath 24a, and hence to the urethra, using clamp 42. Preferably, clamp 42 will not be tightened sufficiently to inhibit transmission of pressure signals if fluid coupling is used. Clamp 42 may comprise a simple ratcheted compression device, although a variety of latches, threaded chocks, and other motion-inhibiting structures might be used.

Referring now to Fig. 5, a closely related catheter 18a includes first and second urethral pressure ports 22a, 22b spaced axially along catheter body 32, preferably having an axial separation in a range from about 1 mm to about 10 mm between the urethral pressure ports. Each urethral pressure port is independently coupled to an associated urethral pressure coupler 38a, 38b via an associated lumen for measuring the local urethral pressure adjacent the associated port. Processor 14 will preferably be capable of deriving the pressuregram by selectively using the highest of the pressures indicated by any of the pressure ports. Hence, by including a plurality of axially separated ports, the sensitivity of the system to axial movement of the catheter within the urethra can be decreased. In alternative embodiments, a catheter body lumen which provides fluid coupling with a vesical port may be used to at least partially fill bladder B in preparation for urodynamic testing.

In another aspects of the present invention, a urethral catheter holder is provided. Fig. 6 shows an exploded view of the assembly of urethra catheter holder 110, comprising a supporting base 120, a suspension housing 122, a catheter securement device 124, a biasing element 126, and a catheter guide 128. Assembled views of catheter holder 110 are shown in Figs. 6A, 6B, 6C, and 6D. As shown in Fig. 6A, a catheter 130 is received longitudinally through catheter holder 110, as shown.

Catheter holder 110 is adapted to hold catheter 130 such that supporting base 120 can remain in contact with the patient's labia while catheter 130 moves longitudinally in response to movement of the patient's urethra when the patient coughs. Accordingly, one advantage of the present invention is that catheter 130 can be positioned to remain in at the same relative location with respect to the patient's urethra when the patient coughs. The ability of catheter securement device 124 to hold catheter 130 to allow for catheter movement in response to urethra movement, without tightly pinching catheter 130 is accomplished by the present novel catheter securement system, as follows.

Referring to Figs. 6E and 6F, catheter securement device 124 preferably comprises a toroidal balloon 141, a generally ring-shaped balloon support mount 142, a pneumatic or hydraulic pressure tube 143, and a catheter guide 128, as shown. Together, toroidal balloon 141, balloon support 142, pressure tube 143, and catheter guide 128 are adapted to slide longitudinally as a unit within the suspension housing 122. A bushing 129, which may be made of Teflon, is provided to enable catheter guide 128 to slide freely through supporting base 120. Biasing element 126, which may preferably comprise a mechanical spring, provides a pre-loading force which gently pushes catheter

guide 128 against the external meatus EM of the patient's urethra 150, (see Fig. 10). Accordingly, catheter guide 128 will move together with the patient's urethra such that catheter guide 128 identically tracks the movement of urethra 150.

- As shown in Fig. 7, catheter 130 is preferably received through an opening 5 123 in suspension housing 122 and passes longitudinally through catheter holder 110, as shown. Toroidal balloon 141 is inflated by way of pressure tube 143, which can be connected a pneumatic or a hydraulic pressure system (not shown). As toroidal balloon 141 is inflated, its center orifice will tend to close as the innermost sides of balloon 141 expand inwardly, thereby gently pushing radially inwardly upon the side of catheter 130 around its circumference, thus holding catheter 130 in a fixed position relative to balloon 10 141.

- Catheter securement device 124, (comprising toroidal balloon 141, support mount 142, pressure tube 143, and catheter guide 128), is adapted to slide 15 longitudinally within suspension housing 122. As can be seen in Figs. 6 and 6C, a groove 145 running longitudinally through suspension housing 122 provides freedom of longitudinal movement for pressure tube 143, which passes therethrough, as shown.

- In preferred aspects of the invention, toroidal balloon 141 is made of silicon rubber, and support housing 122 and catheter guide 128 are made either of aluminum, or a polycarbonate material. It is to be understood, however, that support 20 housing 122 and catheter guide 128 can be made of any suitable bio-compatible material.

- Further structural details of the present invention are seen in the exploded view of Fig. 6. A pair of fasteners 150 can be used to secure housing flange 152 to supporting base 120. Backing plates 154 and 156 can also be provided on opposite sides of catheter securement device 124. Backing plates 154 and 156 may preferably be made 25 of aluminum. Fasteners 158 can be provided for securing backing plates 154 and 156 to catheter securement device 124.

- An alternate embodiment of the catheter securement device is shown in Figs. 12 and 13. The system shown in Figs. 12 and 13 operates similar to catheter system 124, moving to track movement of the patient's urethra, as explained herein. Instead of 30 using a toroidal balloon and balloon support mount, a mechanical clamping system which moves longitudinally in response to urethral movement is provided.

Referring to Fig. 12, a mechanical clamp 170 is provided. Clamp 170 comprises a pair of hard opposite portions 172 and 174 supporting soft inner surfaces 173 and 175 which may be manufactured of silicone or medical tubing. A notch 171 is

provided for supporting a catheter therein as illustrated in Fig. 13. A spring 176 will bias hard opposite portions 172 and 174 together, closing clamp 170 around a catheter received therein. As seen in Fig. 13, clamp 170 can be mounted to a backing 180, wherein backing 180 moves longitudinally in suspension housing 122 under the influence of a 5 biasing element, (functioning in the manner of biasing element 126 as herein described). As can be seen, levers 177 and 179 project out through groove 143. Pinching on levers 177 and 179 causes opposite portions 172 and 174 to separate, such that catheter 130 can be received therein. Levers 177 and 179 move longitudinally in groove 143 when catheter groove 128 and backing 180 move in response to movement of the patient's 10 urethra. Clamp 170 may be secured to backing 180 by a pair of pins 178. It is to be understood that other mechanical clamping systems are possible, all keeping within the scope of the present invention, including the use of both expansion and compression springs to cause the mechanical clamp to securely hold the catheter in position.

In a preferred aspect of the invention, optional leg straps are provided for 15 registering the supporting base 120 of catheter holder 110 against the labia of the patient as catheter guide 128 moves with the urethra. Referring to Fig. 8, catheter holder 110 can be held in position with two leg straps 112 connected at opposite ends to supporting base 120, as shown. Alternatively, as shown in Fig. 9, a stretchable undergarment 160 can be worn by the patient. Undergarment 160 has an opening 162 over which catheter holder 20 110 can be fastened in position by way of four leg straps 113, wherein each of leg straps 113 have a Velcro-type patch 115 at their ends as shown for connecting fastening leg straps 113 directly to stretchable undergarment 160. Leg straps 112 may themselves be secured to slots 148 in supporting base 120 either by hooks (not shown) or by passing an end of each leg strap 112 through slot 160 and then folding the leg strap over upon itself 25 and securing it into position with a Velcro-type fastener.

In another aspect of the present invention, a system for evaluating female urinary incontinence is provided. Preferably, the system for evaluating female urinary incontinence comprises the present urethral catheter system as above described. Referring to Fig. 10, catheter 130 has pressure sensors 132, 134 disposed thereon, as shown. 30 Catheter 130 is preferably inserted through urethra 150 into bladder B. Catheter 130 is then controllably retracted through urethra 150 by a mechanical retractor 160. Accordingly, pressure sensors 132, 134 can be positioned to take pressure measurements at each of the proximal urethra PU (which is located approximately 5-10 mm from the urethro-vesicle junction U-VJ), the mid-urethra MU, (where the vesicle pressure is

greatest), to the distal urethra (which is located approximately 5-10 mm from the external meatus EM). It is to be understood that the present invention can operate with one or more pressure sensors 132, 134 since catheter 130 can be retracted through urethra 150. As can be seen, supporting plate 120 rests against the patient's labia L.

- 5 In a preferred aspect, an anchoring structure for catheter 130 can comprise a catheter positioning surface 131, such as an expandable balloon positioned between the patient's distal urethra DU and external meatus EM to engage soft tissues of urethra 150 so as to inhibit movement of catheter 130 within urethra 150 when the patient coughs. Alternatively, the outer surface of catheter 130 can be textured so as to gently grip against
- 10 the sides of urethra 150, thereby holding catheter 130 in a fixed relative position to urethra 150. In a preferred aspect, a removable sheath is preferably received over the high friction surface such that the catheter can be conveniently inserted into the patient and positioned at a desired location. The sheath is then removed, such that the high friction surface of the catheter engages the walls of the urethra. Alternatively, fluid may
- 15 be injected into the urethra, causing it to expand while the high friction surface catheter is inserted. Removal of the fluid surrounding the catheter will cause the urethra to collapse inwardly, such that the high friction surface of the catheter engages the walls of the urethra.

- Measuring the patient's vesicle and urethral pressures with a pressure-sensing catheter can be accomplished by first moving a pressure sensor on the catheter from the patient's bladder, (at which the vesicle pressure is measured), through the patient's urethra (at which maximum urethral pressure is measured) to determine the maximum urethral pressure, as described above. A urinary catheter with internal or external pressure transducers can be used to take pressure measurements at the proximal urethra, mid-urethra, and/or distal urethra. Typically, such a pressure-sensing catheter is first introduced through the urethra into the bladder. The pressure-sensing catheter is then withdrawn through the urethra with pressure measurements taken at the proximal urethra (being 5-10 mm from the urethro-vesicle junction), the mid-urethra (being the point of maximum resting urethral pressure) and the distal urethra, (being 5-10 mm from the external meatus). For generating a pressuregram, the urethral pressure sensor will generally be positioned at the maximum pressure location, often called the mid-urethra, as described above.

Abdominal pressure transients or pulses can conveniently be generated simply by having the patient cough with different amounts of effort. For example, a mild

couch would generate a minimal increase in abdominal pressure, whereas a more intense cough will generate a greater abdominal pressure. The increase in abdominal pressure will cause both the urethral pressure (including the maximum urethral pressure) and the vesicle pressures to increase. A continence margin can be defined by the difference
5 between the patient's maximum urethral pressure and the vesicle pressure.

The pressures measured by pressure sensor 130 are received by computer system 162 and are displayed as a pressuregram on display terminal 164. Fig. 11 shows an exemplary pressuregram in which urethral pressure is plotted against vesicle pressure. The pressuregram shows the relationship between urethral and vesicle pressure for two
10 different patients for different abdominal pressures caused by the patient coughing. Patient A's urethral pressure always exceeds her vesicle pressure, therefore patient A remains continent. For patient "B", however, her urethral pressure may be above or below her vesicle pressure, (as signified by her pressure data dropping below line
15 $P_{urethral} = P_{vesicle}$), thus indicating incontinence at certain abdominal pressures. More specifically, above an equilibrium pressure P_e , leakage of urine will likely occur.

Referring now to Fig. 14, a tissue engaging structure 190 includes a central passage 192 for receiving the catheter, and side cutouts 194 which define channels when a positioning surface 196 of the tissue engaging structure engages the soft tissues adjacent the external meatus. These channels allow a system operator to observe when leakage
20 occurs during pressuregram testing, and may also allow observation of the urethra. Tissue engaging structure 190 may be fabricated from a transparent polymer material to further minimize any obstruction of the physician's view, and such tissue engaging structures may be incorporated into many of the anchoring structures described above.

A still further alternative pressure sensing catheter 18b is illustrated in
25 Figs. 15A and 15B, here having a two-lobed balloon 48a which defines channels when inflated within urethra U. Hence, the tissue engaging and positioning surface of the anchoring structure may optionally engage the tissue along the urethra

Referring now to Fig. 16, a vacuum secured pressure sensing catheter 18c includes at least one (and preferably an array of) vacuum port 204. The vacuum port
30 array will preferably comprise between about 12 and 30 small openings, each typically having a diameter in a range from about .010 inches to about .040 inches. Vacuum ports 204 will preferably open to a common lumen of catheter body 32 for coupling to an external vacuum source via a vacuum connector 206, although two or more vacuum lumens could alternatively be used. In the exemplary embodiment, two linear arrays of

10 ports each are offset by about 90 degrees about the axis of the catheter body, thereby defining 10 pairs of ports. The vacuum ports are disposed within 5 cm proximally and/or distally of urethral pressure sensor 22 so that the ports can engage the tissue along the urethra when the urethral pressure sensor is disposed at the target maximum urethral
5 pressure location.

In use, vacuum catheter 18c will be inserted into the urethra while the vacuum ports are inactive. Once urethral pressure sensor is axially positioned at the maximum urethral pressure location, vacuum ports 204 are activated, securing the catheter body around the ports into fixed engagement with the urethral wall along the
10 urethra. As no anchoring structure protrudes from catheter body 32, flow-induced changes in pressures during urodynamic testing may be avoided.

Yet another alternative pressure sensing catheter 18d is illustrated in Fig. 17. Here, an array of urethral pressure sensors 22' include a series of individual pressure sensors which are axially distributed along catheter body 32. Preferably, the individual
15 pressure sensors are separated by less than 10 mm, and ideally by less than 5 mm so as to allow at least one of the pressure sensors to accurately approximate the peak urethral pressure whenever the maximum pressure is disposed along the array. As described above, the individual pressure sensors may comprise piezo-electric transducers carried by the catheter body, optical pressure sensors, fluid ports fluidly coupled to external
20 transducers, or the like. Array of transducers 22' thereby reduces the sensitivity of the pressure sensing system to positioning of the catheter, allowing the processor to select a maximum urethral pressure even if the catheter moves during testing, and also giving a broader range for placement of the catheter. As was also described above, a fluid fill coupler 208 allows fluid to be introduced into the bladder via a bladder fill port 210 prior
25 to testing.

Sample data and pressuregrams are illustrated in Figs. 18-22. The dataset of Fig. 18 illustrates maximum urethral and vesicle pressures taken substantially simultaneously at sampling intervals and transmitted by the pressure sensing system to the processor, and may also show abdominal pressure. The processor stores the sampled
30 pressures and also plots the pressuregram in real time, for example, while the test is underway and the catheter remains affixed in position. Multiple pressure pulse plots can be superimposed on the display to illustrate the repeatability of the measurements. The operator has the option of refreshing the screen as desired to view results in isolation.

Pressuregram 212 illustrated in Fig. 19 was taken with the patient in a sitting position, and shows a plot representative of a continent woman. As PU appears to rise faster than PV during the pressure pulse, there does not appear to be any point at which a pulse will lead to a leakage event. As little or no catheter movement occurred

5 during this test taken in a sitting position, results remain repeatable throughout three separate pressure pulses induced by three hard coughs. In contrast, pressuregram 214 of Fig. 20A, which was taken with the patient in a standing position, illustrates how results can be altered by movement of the catheter. As the results here appear inconsistent, the test can be rerun. Catheter movement can also produce apparently consistent results, as

10 can be understood with reference to Fig. 20B, which appears to show the vesicle pressure will exceed the urethral pressure above the equilibrium pressure Pe. The processor can calculate Pe by extrapolating a curve-fit approximation of the pressuregram plot. Despite the apparent exceeding of the equivalence pressure, no leakage was observed. The catheter anchoring structure described above can substantially improve reliability of these

15 pressuregram plots.

Referring now to Figs. 23A-C, the invention also provides pressure profile systems 250a, 250b, and 250c (collectively referred to as pressure profile systems 250) including axial position sensors so that the system can accurately measure and plot urethral pressure along the length of urethra U. Rather than attempting to translate a

20 urethral pressure sensor along the urethra at a constant rate, pressure profile systems 250 provide axial pressure sensor position measurements in correlation with pressure measurements from the urethral pressure sensor. These associated position and pressure measurements allow an accurate pressure plot of pressures along the length of the urethra to be generated regardless of variations in the rate of movement of the sensor, as the

25 plotted data can be independent of the measurement time.

An optical encoder position sensing system 250a is schematically shown in Fig. 23A. A housing 252 rotatably supports a pickup wheel 254 in rolling engagement with catheter 18. An optical pickup 256 is also mounted to housing 252, and the housing may be supported in a fixed position by engagement between a surface 260 of the housing

30 and a tissue such as thigh 258 or the like (see Fig. 23B), by coupling the housing to an anchoring structure axially affixed relative to the urethra as described above, by independently supporting the housing, or the like. If an anchoring structure of the pressure sensing system is used to support the housing, the anchoring structure will often be capable of allowing axial movement of the catheter, as was described above.

When catheter 18 is moved proximally, whether manually or with an automated puller mechanism, a switch 261 can be actuated so that the processor measures axial movement of catheter in correlation with the pressure measurements from the urethral pressure sensor of the catheter. More specifically, pickup 256 transmits signal 5 via cable to processor 14 in response to rotation of wheel 254, and the processor determines and stores an axial position of catheter 18 and/or pressure sensor 22 during pressure measurements using the signals from position sensing system 252.

Figs. 23B and 23C illustrate alternative position sensors of related pressure profile systems. In a linear position sensor 250b, a linear sensor such a linear 10 potentiometer 266 is actuated by movement of catheter 18. Catheter 18 may be coupled to the wiper of potentiometer 266 by a quick release clamp 268, thereby providing an absolute analog position signal to processor 14. Direct optical position sensor 250b includes an optical pickup which directly reads optical measurement indicators 270 of 15 catheter 18, the indicators being similar to bar codes. Catheter 18 will typically include regularly spaced markers for visual reference by the system operator, and indicators 270 may be incorporated into these markers. Regardless of the specific positioning system, the signal will preferably indicate the direction (distal or proximal) and amount of 20 catheter travel, permitting the operator to concentrate on manipulation of the catheter instead of data system operation.

Fig. 21 shows an arrangement of information which may be included in 25 display 16 to facilitate incontinence diagnosis using the system of Fig. 1. Along with pressuregram 218, PV, and particularly, PU are shown in real time so that the operator can use display 16 to help position the urethral sensor at the location of maximum urethral pressure, the pressures preferably being sufficiently large to be read by persons of average visual acuity at a distance of at least 8 feet. Optionally, a pressure plot 220 of PU 30 and/or PV (and in many cases, abdominal pressure PA) will often be taken and plotted throughout a sampling time, that is, as pressure verses time. Alternatively, using the devices of Figs 23A-C, pressure plot 220 may show PU and/or PV plotted against an axial distance, such as along the length of urethra U.

Fig. 22 schematically illustrates a method 230 for diagnosing and treating 35 a patient using the diagnostic systems described above. The urethral and vesicle pressure sensors will be calibrated, and if appropriate, some or all of the pressure sensing system may be sterilized prior to testing. The pressure sensing catheter is positioned, preferably with reference to the display showing urethral pressure PU, so that the urethral pressure

sensor is aligned with the location of the maximum urethral pressure when the patient is at rest, and so that the vesicle pressure sensor is exposed to bladder pressure. The pressure sensors may also be rotationally positioned by rotating catheter 18. The aligned catheter is held in position using any of the anchoring structures described above. Data transfer, storage, and/or display is initiated, and a pressure pulse is initiated, typically by having the patient cough. At least one pressuregram is generated from the urethral and vesicle pressure during the pressure pulse.

In many cases, it will be advantageous to generate a plurality of pressuregrams with pressure pulses of varying intensities, and/or with the patient in a variety of positions, such as standing, sitting, supine, and the like. Using the pressuregram, a desired remodeling of the pelvic support tissues can be determined so as to inhibit incontinence. The desired remodeling may then be performed as described below.

The present invention also provides methods, devices, and systems which enhance the structural support provided by a body's tissues, particularly as a therapy for incontinence. The techniques of the invention will generally involve contraction of tissue, promoting the formation of scar tissue so as to stiffen a tissue structure, and/or the attachment of two adjacent tissues (which are normally free to slide relative to each other) to each other. Energy may be directed from a probe into one or more fascial tissues of the pelvic support system. The energy may lead to the formation of stiff scar tissue, and/or it may attach adjacent fascial tissues together by fusing, cross-linking of collagen, the formation of adhesions, or the like. Optionally, the energy may also cause contraction of the fascial tissue by heating this collagenous layer to a contraction temperature over about 60° C. Alternatively, stiffening and/or attachment of adjacent fascial layers may be provided without significant contraction, as scar tissue can be promoted by heating the fascia to temperature below that at which significant contraction takes place, for example, over about 45° C.

The techniques of the present invention will often be used to stiffen or attach fascia, tendons, and other collagenous tissues, preferably without ablation of these collagenous tissues. As used herein, this means that collagenous tissues are not removed and their function (particularly their structural support function) is not destroyed. Histologically, some tissue necrosis may occur, and the structural strength of the tissues may initially decrease immediately after treatment. Nonetheless, the treated tissues will generally continue to provide at least some structural support, and their structural strength

should increase during the healing process so that the healed tissue has preferably the same ultimate structural strength as, and often greater stiffness (for example, having a lower modulus of elasticity so as to stretch less under tension) than before treatment.

The hammock-like endopelvic fascia described above may be damaged or missing, particularly after pregnancy, so that the support of the genitourinary tract is instead provided by a variety of fascial layers, muscular tissues, ligaments, and/or tendons within the pelvis. Hence, the treatment of the present invention may be directed at a variety of tissue structures defining the pelvic floor and/or diaphragm (including: anterior sacro-coccygeal ligament; arcus tendineus fasciae pelvis (ATFP), the white line of the pelvis; fasciae of the obturator internus muscle; the arcus tendineus levator ani or "picket fence" to the iliococcygeus portion of the levator ani muscle; bulbocavernosus muscle; ischiocavernosus muscle; urethrovaginal sphincter; m. compressor urethrae muscle; and m. sphincter urethrovaginal muscle which replaces deep perineal muscle); structures of the bladder and urethra (including: urethrovesical fascia; detrusor muscle; and the pubo-coccygeus muscle which relaxes to open the bladder neck, initiating micturation); structures of the vagina (including: vagino-uterine fascia, lamina propria-the dense connective tissue layer just under the epithelium; pubo-urethral or puboprostatic ligaments; pubo-vesicle ligament and posterior pubo-urethral or pubo-prostatic ligament; pubovesicle muscle, a smooth muscle that is integrated with the pubo-vesicle ligament; and pubocervical fascia which attaches to the AFP); structures of the uterus (including: round ligament; sacrouterine ligament; and broad ligament); and structures of the bowel (including: rectal fascia and Mackenrodt's ligament).

The effects of excessive elasticity of the pelvic support tissues are illustrated in Figs. 24A-C. In Fig. 24A, a pressure pulse P moves bladder B from an initial position 330 to a lowered position as shown. As endopelvic fascia EF stretches excessively in this case, the fluid pressure within the bladder advances into the bladder neck and down urethra U. Leakage may result in part because the endopelvic fascia allows the bladder to drop below its initial position, at which fluid pressure within the bladder actually helps to seal the bladder neck. Perhaps even more importantly, stretching of the endopelvic fascia may alter the timing of pressure pulse transmission to urethra U.

When a continent woman coughs, the pressure in the urethra will often increase more than one-tenth of a second prior to the increase in bladder pressure. In women with stress incontinence, the bladder pressure may rise first. The effect of a

stretched endopelvic fascia on this difference in timing can be understood with reference to Figs. 24B and C.

Fig. 24B schematically illustrates a simplified theoretical pelvic support system for a woman with stress incontinence. When pressure pulse P first begins to act on urethra U, the bladder, bladder neck, and urethra are disposed at initial position 330. As endopelvic fascia stretches significantly under the effects of pressure pulse P, there is a significant time delay between initiation of the pressure pulse and transmission of a closing force against urethra U. For example, urethra U may be closed by transmission of pressure pulse P between one-tenth and one-half second after pulse is imposed on the bladder. Hence, leakage would occur during this time delay.

This situation is different for a continent woman having the simplified theoretical pelvic support system illustrated in Fig. 24C. In this case, endopelvic fascia EF stretches much less under the influence of pressure pulse P, so that the time delay between initiation of the pressure pulse and transferring sufficient force to urethra U to effect closure is significantly less. More specifically, an increase in the modulus of elasticity of the endopelvic fascia and the pelvic support system shortens the response time of the tissue system to momentary stress. By treating the endopelvic fascia to increase its stiffness, the decent time of the pelvic viscera during a cough will be much shorter than an untreated, highly elastic tissue.

It should be noted that the continent woman's support structure schematically illustrated in Fig. 24C has an initial position 330' in which the endopelvic fascia EF is more taut than the incontinent woman's structure illustrated in Fig. 24B. In other words, excessive length of the pelvic support tissues may add to the delay and bladder movement, independently of the effects of excessive elasticity. Hence, in many cases, it will be beneficial to both increase the modulus of the endopelvic fascia and decrease its length so as to improve continence. Advantageously, the collagenous fascial tissues may be selectively contracted using many of the same system components described herein, often by heating this collagenous tissue to a slightly higher temperature than that used to promote scar tissue formation.

Referring now to Fig. 25, a urinary incontinence diagnosis and treatment system 310 generally includes a diagnostic subsystem 312 for diagnosing stress incontinence and a treatment subsystem 314 which provides a therapy for a specific patient in response to a specific diagnosis. Diagnostic system 312 generally includes a catheter 316 for sensing pressures in bladder B and in urethra U, and a holder 318 which

helps keep the catheter in position when the bladder and urethra move during a pressure pulse. Signals from catheter 316 are transmitted to processor 320, which displays a pressuregram 322 on display 324. Pressuregram 322 indicates a change in urethral pressure relative to a change in vesicular pressure.

- 5 As was described above, catheter 316 again includes pressure sensors 326. Pressure sensors 326 sense vesicular pressure within bladder B, and sense a maximum urethral pressure within urethra U, with the location of this maximum urethral pressure sometimes being referred to as the mid-urethra MU. To maintain the location of catheter 316 during a pressure pulse, holder 318 supports the catheter while allowing the catheter
10 to move with the external meatus EM.

- To maintain the position of catheter 316 within urethra U, the catheter may include a balloon which generally engages the surrounding urethra, or holder 318 may include a surface which engages, and which supports the catheter relative to, the external meatus EM. This allows catheter 316 to provide pressure signals which accurately reflect
15 the urethral and vesicular pressure throughout a pressure pulse, which may be induced by having a patient cough, by applying an external impulse against the patient's abdomen, or the like. Processor 320 can record these pressures throughout multiple pressure pulses for displaying as pressuregram 322. Generally, where urethral pressure remains higher than vesicular pressure (above the $P_u = P_v$ line on the pressuregram) leakage will not occur.
20 However, where vesicular pressure increases faster than urethral pressure during a pressure pulse, a sufficiently strong pulse may produce leakage.

- To increase the rate of change of the urethral pressure for each increment of change in the vesicular pressure, treatment system 314 may be employed to increase a modulus of the patient's pelvic support system. Often, treatment system 314 will
25 selectively promote formation of scar tissue along a fascial plane. To remodel tissues of the pelvic support system, power supply 326 directs RF current to selected pairs of electrodes on probe 328 under the direction of processor 320. Here, selective heating commands from processor 320 are implemented by a separate switching unit 329. It should be understood that in alternative arrangements, the switching unit may be
30 incorporated into processor 320, power supply 326, or probe 328, and that separate processors may be provided for the diagnostic and treatment subsystems. In many embodiments, feedback on the course of treatment will be provided in the form of feedback signals FS transmitted from probe 328 to processor 320.

The use of probe 328 of the system of Fig. 25 is illustrated in more detail in Fig. 26A. Probe 328 includes an array of electrode pairs 336 mounted to a probe body 338. Probe body 338 may optionally be supported on a shaft, which will typically contain the wires coupling electrode pairs 336 to power supply 326 (see Fig. 25). Electrode pairs 5 336 are selectively energized by the processor of system 310, so as to transmit sufficient energy to the endopelvic fascia to effect the desired treatment. Hence, processor 320 can tailor the treatment for a specific patient's diagnosis, for example, by varying the area of and energy delivered to target region 332 so as to selectively shrink and/or stiffen the endopelvic fascia layer sufficiently to maintain the urethral pressure above the vesicular 10 pressure throughout a pressure pulse.

Electrodes 336 indirectly engage surface S of endopelvic fascia EF on either side of urethra U. Optionally, the probe may include temperature sensors so as to provide a feedback signal FS to processor 320 so as to maintain the temperature of the endopelvic fascia within a target temperature range. Optionally, the target temperature 15 range may be sufficient to promote scar tissue formation and/or attachment of the endopelvic fascial layer, and may be insufficient to induce shrinkage of the endopelvic fascia. Alternatively, both scar tissue formation and shrinkage may be effected simultaneously. Preferably, probe 328 is used in a static position so that the treatment area is controlled by processor 320 via switching unit 329 selectively applying power to 20 some or all of electrode pairs 336, the number and location of electrode pairs, the heat time, and the heat temperature being sufficient to achieve the desired result.

A laparoscopic device and method for directly heating endopelvic fascia EF can be understood with reference to Fig. 26B. Laparoscopic probe 342 includes a shaft supporting an electrode pair 336 relative to a handle. A variety of electrode pair configurations might be used. Preferably, a port will be disposed adjacent and/or between electrodes 336 to allow a small amount of irrigation flow before and/or during the treatment. This irrigation flow may comprise a conductive fluid such as saline or a non-conductive fluid, and will ideally be sufficient to avoid the accumulation of residue on the electrode pair surfaces. Laparoscopic probe 342 will generally be used in a laparoscopic 25 procedure using a superior approach, typically under the direction of a laparoscope 350 inserted near the patient's mid-line (for example, adjacent the belly button). The handle 346 is manipulated so as to "paint" bipolar electrode 36 across the endopelvic fascia 30 surface until the target region has been sufficiently heated.

Fig. 26C illustrates a still further alternative probe for use with the system of Fig. 25. In this embodiment, a transvaginal bipolar probe 354 includes an electrode pair 336 which is cooled by fluid conduits 356. The fluid conduits cool the intervening tissue between bipolar probe 354 and endopelvic fascia EF via electrodes 336, and via the probe surface between the electrodes. Similarly, the tissue disposed beyond the endopelvic fascia (in this case a wall of bladder B) is cooled, here by circulation of a cooled solution within the bladder. Once the intervening tissue of the vaginal wall VW (and the bladder B beyond the target region of endopelvic fascia EF) are cooled sufficiently, RF current is transmitted between the electrodes to heat the endopelvic fascia. Advantageously, the pre-cooling can redirect the current flux 358 from the intervening and adjacent tissues to a desired flux pattern 360. Feedback on the pre-cooling and heating temperatures may be provided by needle-mounted temperature sensors 362 mounted to the probe, and/or by temperature sensors mounted to the probe surface.

A variety of treatment modalities may be used to effect the desired tissue remodeling. Treatment modalities may include thermal, electrosurgical, laser, focused ultrasound and/or microwave, a variety of bioactive or biochemical agents including local drug delivery, caustic compounds, pleurodesis agents, sclerosing agents, growth factors, surgical sealants and/or the like. When bioactive agents are used, the invention may employ talcum, tetracycline and derivatives, bleomycin, sodium hydroxide, blood, mitomycin, doxycycline, mitoxatrone, dilute acids, absolute ethanol, silver nitrate, ethanolamine oleate, polidocanol, N-butyl-2-cyanoacrylate and/or any of a wide variety of available compounds being marketed.

While the exemplary embodiments of the present invention have been described in some detail, by way of example and for clarity of understanding, a variety of changes, modifications, and adaptations will be obvious to those of skill in the art. Hence, the scope of the present invention is limited solely by the appended claims.

WHAT IS CLAIMED IS:

1 1. An apparatus for evaluating urinary incontinence of a patient, the
2 patient having a urethra extending from a bladder to a urethral opening with a maximum
3 urethral pressure disposed therebetween, the system comprising:

4 a pressure-sensing system comprising an elongate body having a proximal
5 end and a distal end, a vesicle pressure sensor disposed adjacent the distal end for
6 measuring fluid pressure within the bladder, and at least one urethral pressure sensor
7 disposed proximally of the vesicle pressure sensor for measuring urethral pressure;

8 an anchoring structure disposed along the elongate body, the anchoring
9 structure adapted to engage a tissue surface comprising or adjacent the urethra so as to
10 maintain alignment between the urethral pressure sensor and the maximum urethral
11 pressure when a pressure pulse moves the urethra; and

12 a processor coupled to the pressure-sensing system, the processor
13 calculating a relationship between the urethral pressure and the vesicle pressure.

1 2. The apparatus of claim 1, wherein the relationship comprises a
2 pressuregram, and further comprising a display showing the pressuregram in real time to
3 a system operator disposed adjacent the patient, the pressuregram comprising a slope
4 defined by an increase of the measured vesicle pressure relative to an increase of the
5 measured urethral pressure.

1 3. The apparatus of claim 1, wherein the relationship is calculated
2 from a plurality of pressure pulses.

1 4. The apparatus of claim 1, wherein the relationship is independent
2 of time.

1 5. The apparatus of claim 1, wherein the anchoring structure
2 comprises a radially expandable structure.

1 6. The apparatus of claim 5, wherein the anchoring structure is
2 disposed proximally of the vesicle pressure sensor and has at least one axial channel, the
3 channel allowing free transmission of urine through the urethra when the expandable
4 structure is expanded to inhibit movement of the sensor system relative to the urethra.

1 7. The apparatus of claim 6, wherein the expandable structure
2 comprises a balloon having an inflated cross-section defining the at least one channel.

1 8. The apparatus of claim 5, wherein the expandable structure is
2 disposed distally of the at least one urethral pressure sensor and has a proximally oriented
3 surface for engaging the bladder adjacent the urethra, the at least one pressure sensor
4 capable of measuring the maximum urethral pressure at a variable distance from the
5 expandable structure, the anchoring structure further comprising a distally oriented tissue-
6 engaging surface positionable along the elongate body for engaging an external meatus
7 adjacent the urethral opening so as to axially affix the urethral pressure sensor relative to
8 the maximum urethral pressure between the distally oriented surface and the proximally
9 oriented surface.

1 9. The apparatus of claim 1, wherein the anchoring structure
2 comprises a distally oriented surface adapted for engaging an external meatus adjacent the
3 urethral opening, the distally oriented surface variably positionable relative to the urethral
4 pressure sensor for alignment of the urethral pressure sensor with the maximum urethral
5 pressure.

1 10. The apparatus of claim 9, further comprising a support
2 longitudinally movable relative to the distally oriented surface, and a biasing device
3 coupling the support relative the distally oriented surface to urge the distally oriented
4 surface distally against the external meatus.

1 11. The apparatus of claim 1, wherein the anchoring structure
2 comprises at least one vacuum port oriented to engage a tissue along the urethra so as to
3 inhibit movement of the urethral pressure sensor relative to the maximum urethral
4 pressure.

1 12. The apparatus of claim 11, wherein the anchoring structure further
2 comprises a vacuum system coupled to the vacuum port.

1 13. The apparatus of claim 1, wherein at least one of the sensors
2 comprises a port coupled to a transducer by a fluid lumen.

1 14. The apparatus of claim 1, wherein at least one of the sensors
2 comprises a piezo-resistive transducer or an optical pressure sensor.

1 15. The apparatus of claim 1, wherein the at least one urethral pressure
2 sensor comprises a plurality of axially separated sensors exposed to a plurality of
3 differing urethral pressures, the processor selectively couplable to each sensor so as to
4 calculate the relationship when the maximum urethral pressure moves between the
5 plurality of urethral pressure sensors.

1 16. A urethral catheter holder, comprising:
2 a supporting base;
3 a suspension housing mounted to the supporting base;
4 a catheter securement device adapted to hold a catheter passing
5 longitudinally therethrough, the catheter securement device being adapted to slide
6 longitudinally within the suspension housing; and
7 a biasing device adapted to push the catheter securement device against the
8 external meatus of a patient's urethra.

1 17. The catheter holder of claim 16, wherein the catheter securement
2 device comprises:
3 a torroidal balloon;
4 a generally ring-shaped balloon support mount surrounding the torroidal
5 balloon; and
6 a pneumatic or hydraulic pressure tube for inflating and deflating the
7 torroidal balloon, the pressure tube passing through the balloon support mount.

1 18. The catheter holder of claim 17, wherein,
2 the pressure tube extends from the torroidal balloon to a position external
3 to the suspension housing.

1 19. The catheter holder of claim 18, wherein the pressure tube moves
2 longitudinally in a groove in the suspension housing as the balloon support mount slides
3 longitudinally within the suspension housing.

1 20. The catheter holder of claim 16, wherein the catheter is received
2 longitudinally through the supporting base and the suspension housing.

1 21. The catheter holder of claim 20, further comprising:
2 a longitudinally extending catheter guide mounted to the catheter
3 securement device.

1 22. The catheter holder of claim 21, wherein the catheter securement
2 device is adapted to move in response to an abdominal pressure pulse.

1 23. The catheter holder of claim 22, wherein the catheter securement
2 device remains in generally the same position relative to a surrounding urethra when the
3 patient coughs.

1 24. The catheter holder of claim 22, wherein longitudinal displacement
2 of the catheter securement device is approximately equal to longitudinal displacement of
3 the urethra of a patient during the pelvic pressure pulse.

1 25. The catheter holder of claim 16, wherein the biasing device is a
2 spring.

1 26. The catheter holder of claim 17, wherein the torroidal balloon is
2 made of silicone rubber.

1 27. The catheter holder of claim 16, wherein the support housing is
2 fabricated of aluminum or a polycarbonate material.

1 28. The catheter holder of claim 16, wherein the supporting base is
2 adapted to register against the labia of the patient.

1 29. The catheter holder of claim 21, wherein the catheter guide is
2 adapted to contact the urethral external meatus of the patient.

1 30. The catheter holder of claim 16, further comprising:
2 a pair of leg straps, with opposite ends of each leg strap fastened to the
3 supporting frame, such that each leg strap is adapted to be wrapped around one of the
4 patient's thighs.

1 31. The catheter holder of claim 16, further comprising:
2 a stretchable undergarment; and
3 a plurality of leg straps, each leg strap being attachable to the supporting
4 frame at one end and to the stretchable undergarment at an opposite end.

1 32. The catheter holder of claim 31, wherein each leg strap is
2 attachable to the stretchable undergarment by a Velcro-type fastener.

1 33. The catheter holder of claim 16, further comprising:
2 a catheter retraction device for withdrawing the catheter from the patient at
3 a controlled speed.

1 34. The urethral catheter of claim 16, wherein the catheter securement
2 device comprises:
3 a mechanical clamp adapted to be longitudinally movable within the
4 suspension housing.

1 35. The urethral catheter of claim 34, wherein the mechanical clamp is
2 secured to a longitudinally movable backing.

1 36. A system for evaluating female urinary incontinence, comprising:
2 a catheter having at least one pressure sensor positioned thereon; and
3 a catheter holder adapted to support the catheter and to allow movement of
4 the catheter in response to a pelvic pressure pulse, wherein the movement of the catheter
5 tracks movement of the urethra of a patient during a pelvic pressure pulse.

1 37. The system of claim 36, further comprising:
2 a computer system in communication with the pressure sensor of the
3 catheter, the computer system being adapted to generate a pressuregram of the
4 relationship between urethral pressure and vesicle pressure in response to changes in
5 pelvic pressure as the pressure sensor on the catheter is moved through the urethra of a
6 patient.

1 38. The system of claim 37, further comprising:
2 a display terminal adapted to display the pressuregram.

1 39. The system of claim 36, wherein the pressure-sensing catheter
2 comprises:

3 a catheter positioning surface positioned to engage soft tissues of the
4 urethra so as to inhibit movement of the catheter within the urethra.

1 40. The system of claim 40, wherein the catheter positioning surface
2 comprises:

3 a high friction surface of the catheter for engaging the surrounding urethra.

1 41. The system of claim 41, further comprising:

2 a removable sheath positioned over the high friction surface of the
3 catheter.

1 42. The system of claim 36, wherein the pressure-sensing catheter
2 comprises:

3 a balloon positioned to engage soft tissues of the urethra so as to inhibit
4 movement of the catheter within the urethra when the balloon is inflated.

1 43. The system of claim 36, wherein the at least one pressure sensor
2 comprises an array with a plurality of pressure sensors separated axially relative to an axis
3 of the catheter.

1 44. A method for evaluating urinary incontinence comprising:

2 introducing a pressure sensor system into a urethra of the patient;

3 aligning at least one urethral pressure sensor of the pressure sensor with a
4 maximum urethral pressure;

5 affixing the aligned urethral pressure sensor of the pressure sensor system
6 relative to a urethra of the patient with an anchoring structure of the pressure sensor
7 system;

8 inducing a pressure pulse in a patient, the urethra moving with the pressure
9 pulse;

10 monitoring a fluid pressure of a bladder during the pressure pulse;

11 monitoring the maximum urethral pressure during the pressure pulse with
12 the pressure sensor by moving the pressure sensor with the urethra via the anchoring
13 structure during the pressure pulse; and

14 comparing the monitored bladder and urethral pressures.

1 45. A data system for use with a mechanism for diagnosing urinary
2 incontinence of a patient, the mechanism producing a pressuregram indicating a
3 pressuregram slope defined by a change of vesicle pressure of the patient relative to a
4 change of urethral pressure of the patient, the vesicle and urethral pressures being
5 measured with a catheter system having a distal end and a proximal end, the data system
6 comprising:

7 a processor coupled to the catheter for receiving a vesicle pressure signal
8 and a urethral pressure signal, the processor generating a pressuregram dataset in real
9 time at least in part from the vesicle and urethral pressure signals; and

10 a display coupled to the processor so as to generate a real time image of
11 the pressuregram from the pressuregram dataset, the display visible from adjacent the
12 proximal end of the catheter.

1 46. The data system of claim 45, wherein a soft tissue of the patient
2 moves with the urethra during a pelvic pressure pulse, and further comprising a catheter
3 positioning surface attached to the catheter, the catheter positioning surface adapted to
4 engage the soft tissue so as to inhibit movement of the catheter within the urethra.

1 47. The data system of claim 46, wherein the positioning surface is
2 insertable along at least a portion of the urethra, the soft tissue being disposed along the
3 urethra.

1 48. The data system of claim 46, wherein the positioning surface
2 comprises a high friction surface of the catheter oriented for engaging the surrounding
3 urethra, and further comprising a removable low friction interface disposable between the
4 positioning surface and the urethra for insertion, the interface comprising a fluid.

1 49. The data system of claim 46, wherein the positioning surface has a
2 cross-section larger than a cross-section of the catheter so as to engage the soft tissue
3 adjacent an external meatus.

1 50. The data system of claim 49, wherein the positioning surface is
2 adjustably affixable along an axis of the catheter.

1 51. The data system of claim 49, further comprising a reaction support
2 and a biasing mechanism supporting the positioning surface relative to the support, the
3 biasing mechanism oriented to urge the positioning surface against the external meatus.

1 52. The data system of claim 51, wherein the biasing mechanism
2 movably supports the positioning surface so that the positioning surface can move at least
3 about 2 cm with the external meatus.

1 53. The data system of claim 51, wherein the positioning mechanism
2 comprises a clear material having a cross-sectional dimension of at least 1/2 inch and at
3 least one passage for monitoring of voiding.

1 54. The data system of claim 45, wherein the processor selectively
2 displays one or more pressure pulses, the program capable of refreshing the display
3 between pressure pulses.

1 55. The data system of claim 45, wherein the display further shows
2 a continence margin defined by a difference between the urethral pressure
3 and the vesicle pressure.

1 56. The data system of claim 45, wherein the display further shows an
2 equilibrium pressure above which the vesicle pressure will exceed the urethral pressure.

1 57. The data system of claim 56, wherein the processor extrapolates
2 the equilibrium pressure using a curve approximation of the pressuregram.

1 58. The data system of claim 45, wherein the processor generates the
2 pressuregram dataset using a windows-based program.

1 59. A system for treatment of urinary stress incontinence of a patient,
2 the patient having a tissue comprising or support the urethra, the bladder neck, or the
3 bladder, the system comprising:
4 a diagnostic system including a urethral pressure sensor, a bladder pressure
5 sensor, and a processor coupled to the sensors, the processor generating an output
6 indicating a desired remodeling of the tissue of the patient; and

7 a probe having an energy transmitting element that controllably delivers
8 energy to the tissue so as to effect the desired remodeling such that the incontinence is
9 inhibited.

1 60. The system of claim 59, wherein the energy transmitting element
2 of the probe controllably delivers the energy in response to the output of the processor.

1 61. The system of claim 59, wherein the processor is coupled to the
2 probe, the processor generating an energy signal, the energy varying with the energy
3 signal.

1 62. A method for treatment of urinary stress incontinence of a patient,
2 the method comprising:

3 sensing a bladder pressure and a urethral pressure;
4 determining a desired remodeling of a tissue comprising or supporting a
5 urethra, a bladder neck, and/or a bladder of the patient from the bladder pressure and the
6 urethral pressure;
7 effecting the desired remodeling of the tissue so that the incontinence is
8 inhibited.

1 63. The incontinence treatment method of claim 62, further comprising
2 generating a pressure pulse in the tissue during the sensing step.

1 64. The incontinence treatment method of claim 63, wherein the
2 pressure pulse is the result of a cough.

1 65. The incontinence treatment method of claim 62, wherein the
2 pressure pulse is generated after effecting partial remodeling of the tissue for use as
3 feedback in the remodeling step.

1 66. A method for treatment of urinary stress incontinence of a patient,
2 wherein a pressuregram of the patient indicates urethral pressure of the patient differs
3 from a vesicle pressure of the patient by a continence margin, the pressuregram having a
4 pressuregram slope defined by change of the vesicle pressure relative to change of the
5 urethral pressure, the pressuregram slope being such that the vesicle pressure will exceed
6 the urethral pressure of the patient above an equilibrium pressure, the method comprising:

7 determining a desired change in a support tissue comprising or supporting
8 the urethra based at least in part on at least one parameter selected from the group
9 comprising the equilibrium pressure, the continence margin, and the pressuregram slope;
10 and
11 remodeling the support tissue by the desired change from the determining
12 step.

1 67: The method of claim 66, wherein the remodeling step comprises
2 directing energy into the support tissue so as to contract the support tissue.

1 68. The method of claim 66, wherein a plurality of pressuregrams are
2 taken with the patient in a plurality of positions selected from the group consisting of
3 standing, sitting, and supine, and wherein the determining step is based on the plurality of
4 pressuregrams.

1 69. A system for evaluating urinary incontinence, the system
2 comprising:
3 a body having a proximal end, a distal end, and a cross-section suitable for
4 insertion into a urethra;
5 a pressure sensor disposed along the body for measuring urethral pressure;
6 and
7 a position sensing system couplable to the body to measure an axial
8 position of the pressure sensor within the urethra.

1 70. The system of claim 69, wherein the pressure sensor generates
2 pressure signals and the position sensing system generates position signals.

1 71. The system of claim 70, further comprising a processor coupled to
2 the pressure sensor and to the positioning system, and a display coupled to the processor,
3 the display showing a plot of associated urethral pressures and axial positions, the plot
4 being independent of rate of movement of the body relative to the urethra.

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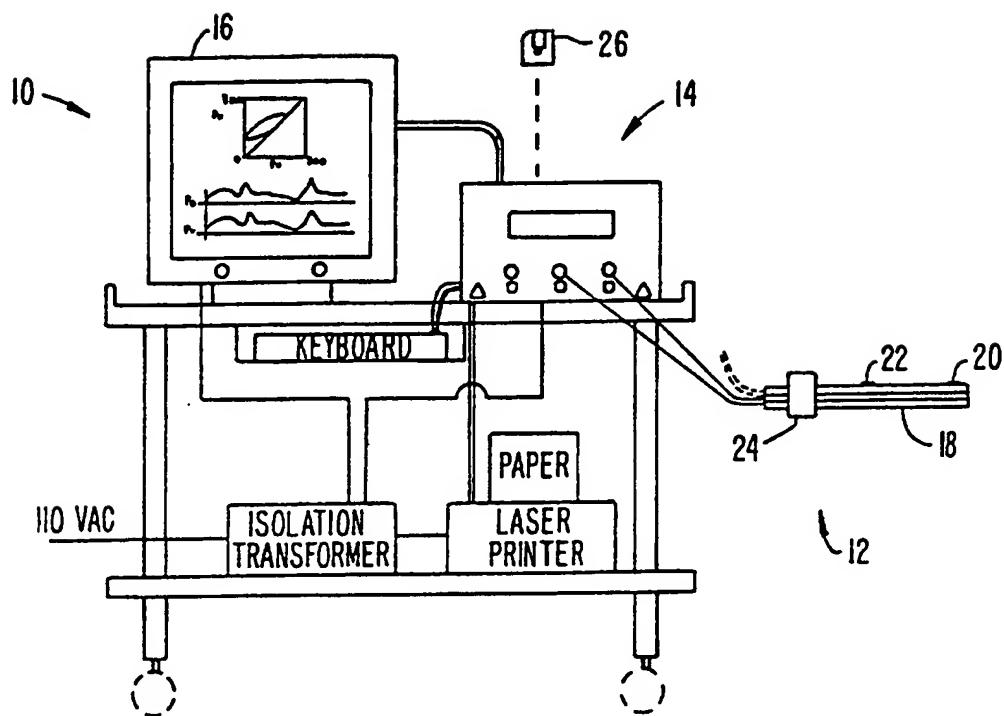


FIG. 1.

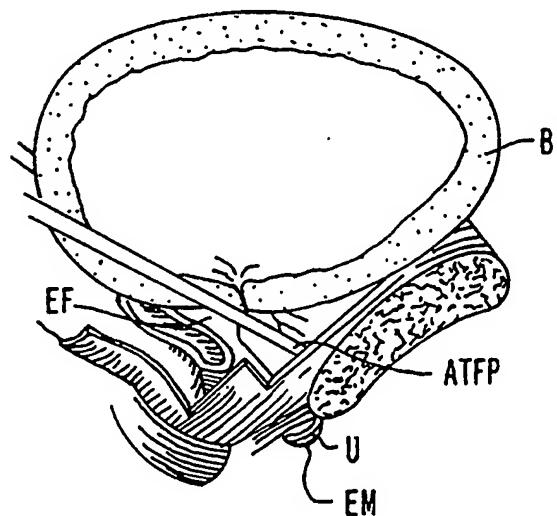


FIG. 2.

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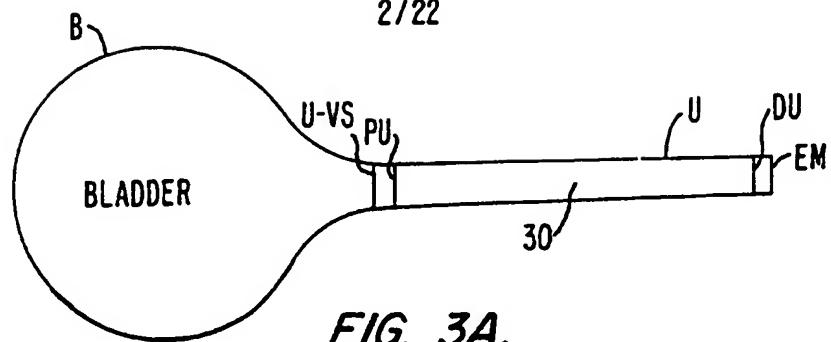


FIG. 3A.

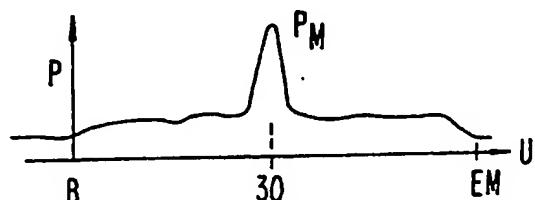


FIG. 3B.

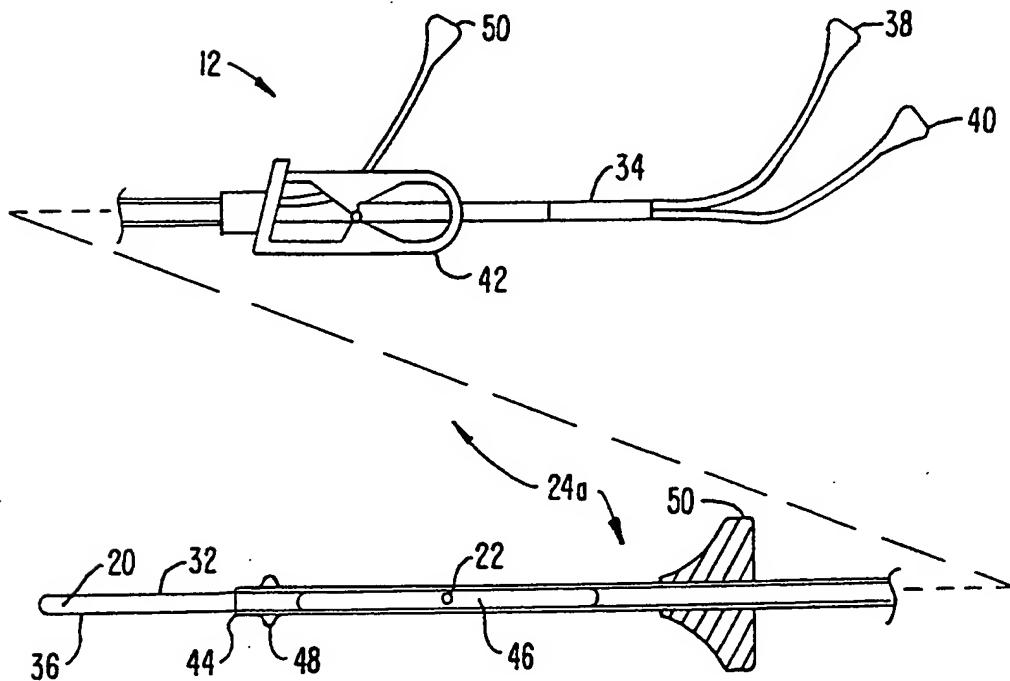


FIG. 4.

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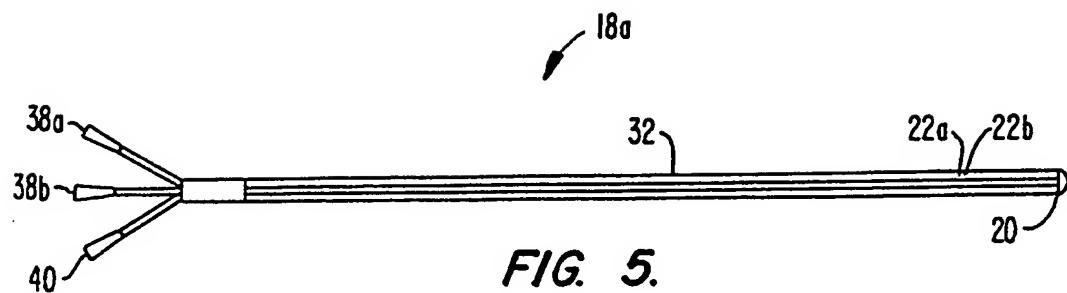


FIG. 5.

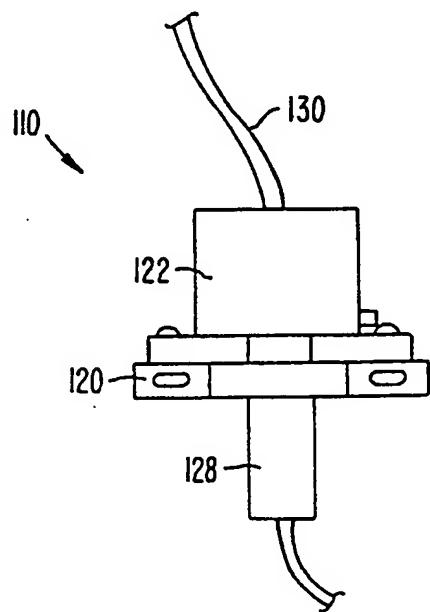


FIG. 6B.

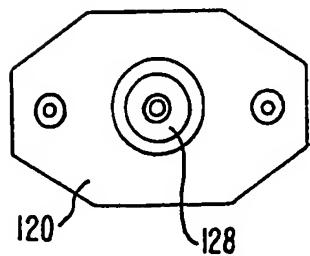
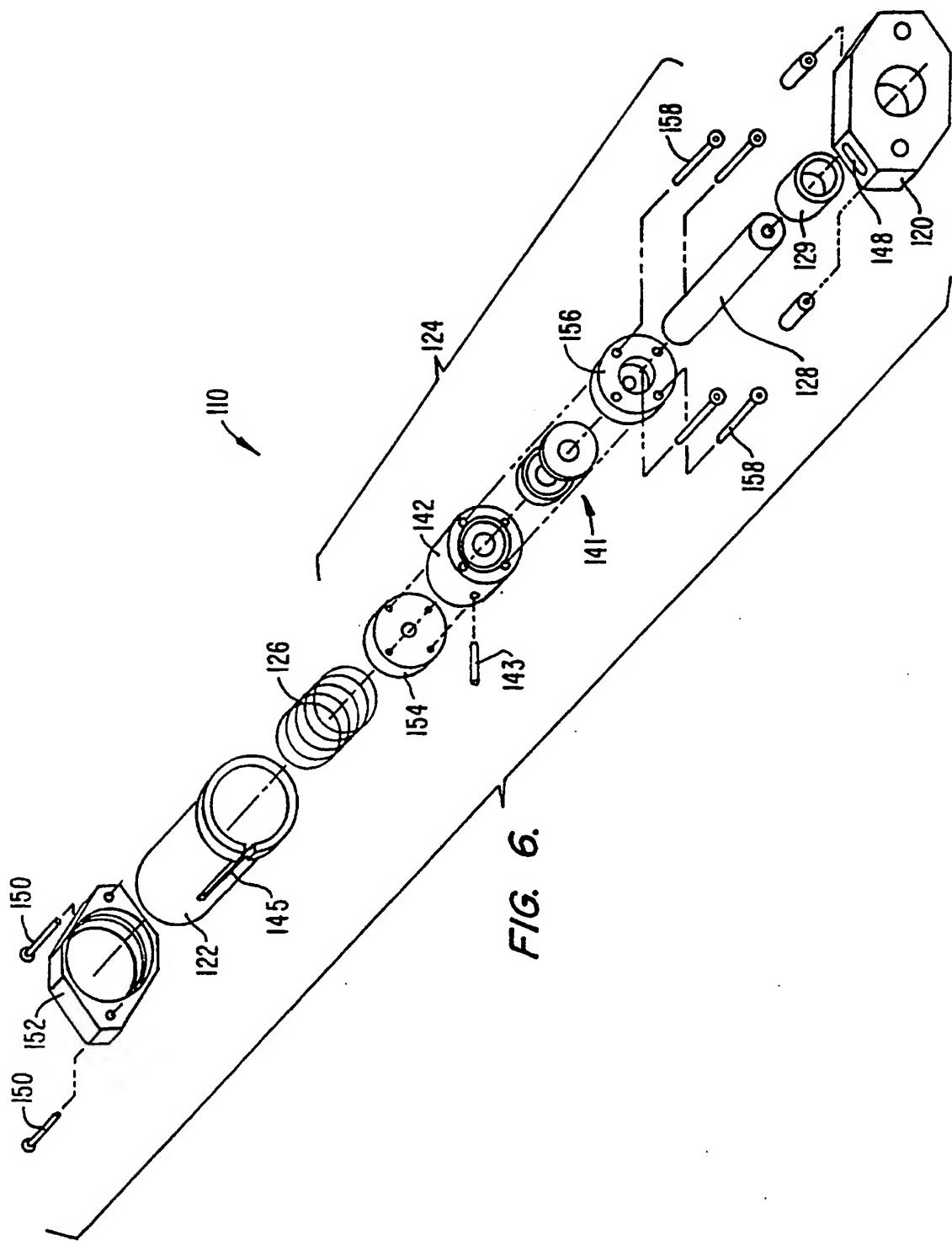


FIG. 6A.



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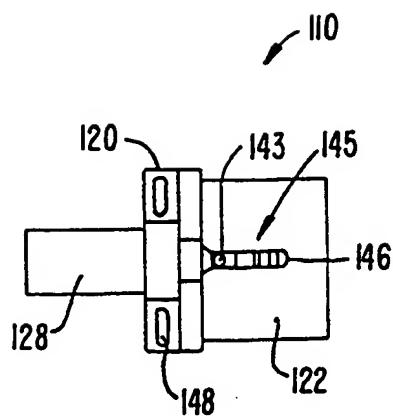


FIG. 6C.

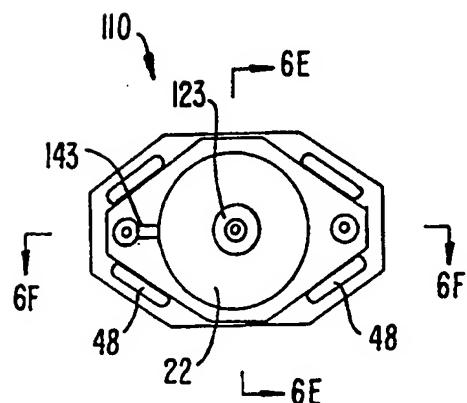


FIG. 6D.

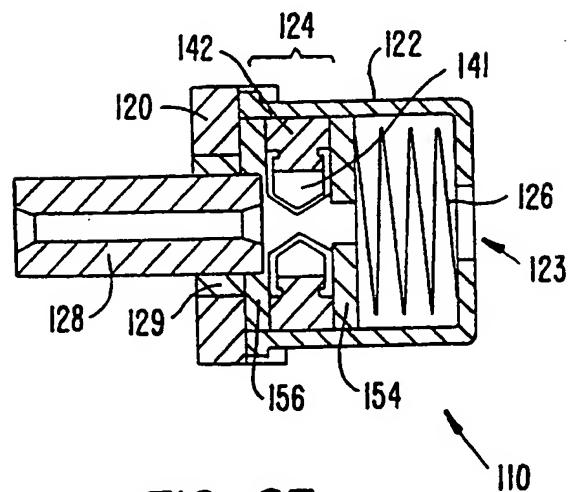


FIG. 6E.

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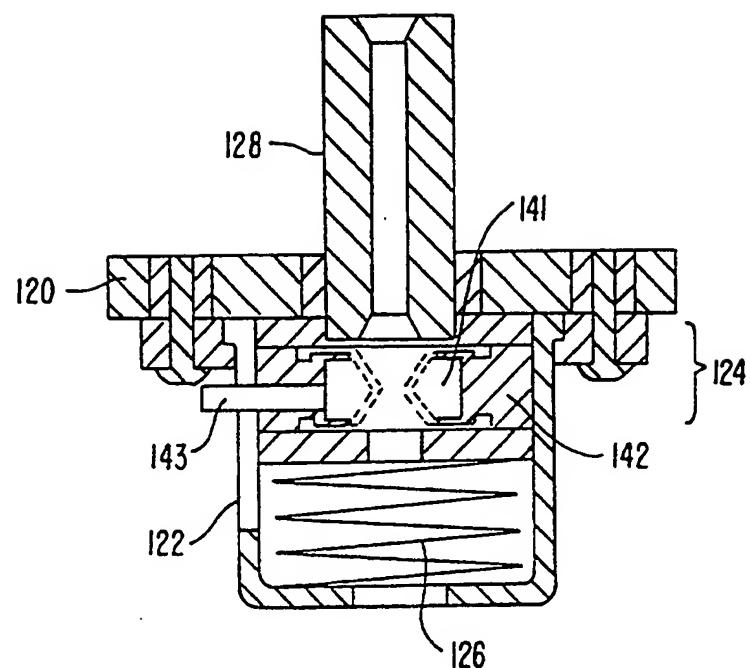


FIG. 6F.

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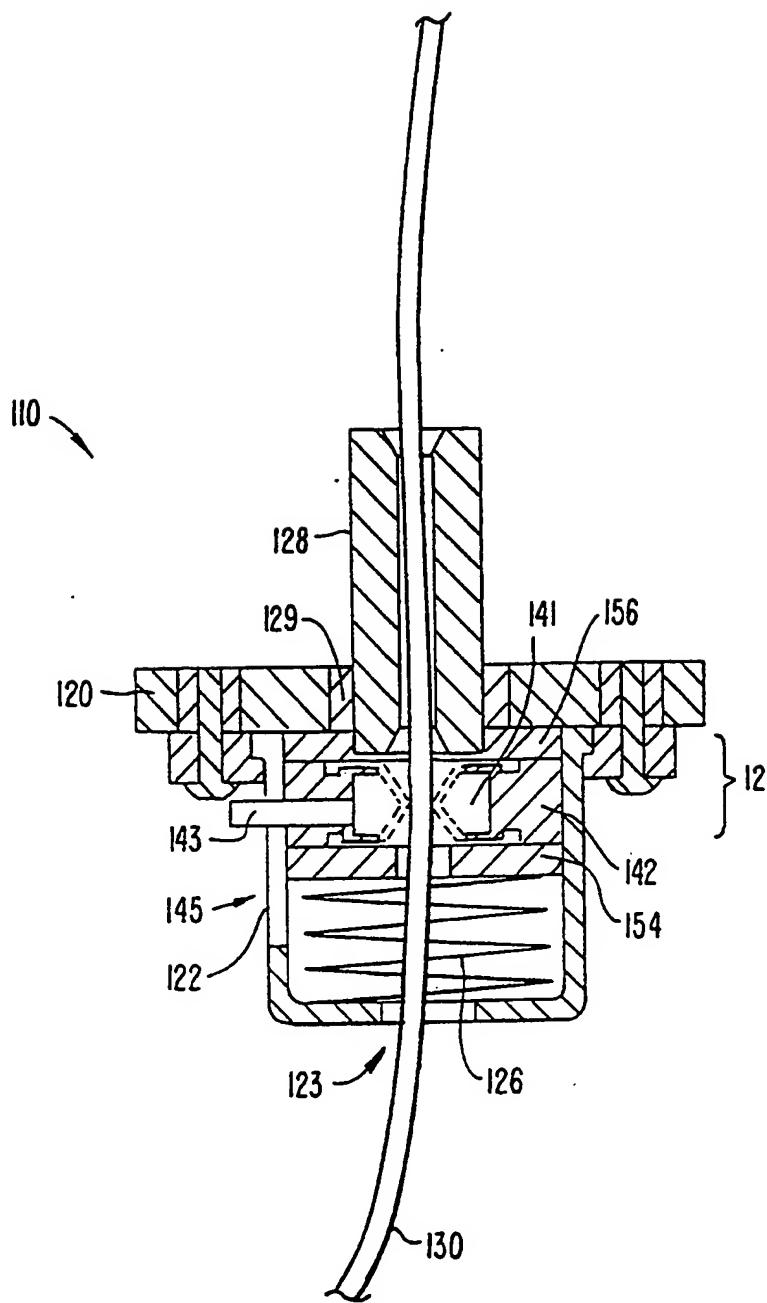


FIG. 7.

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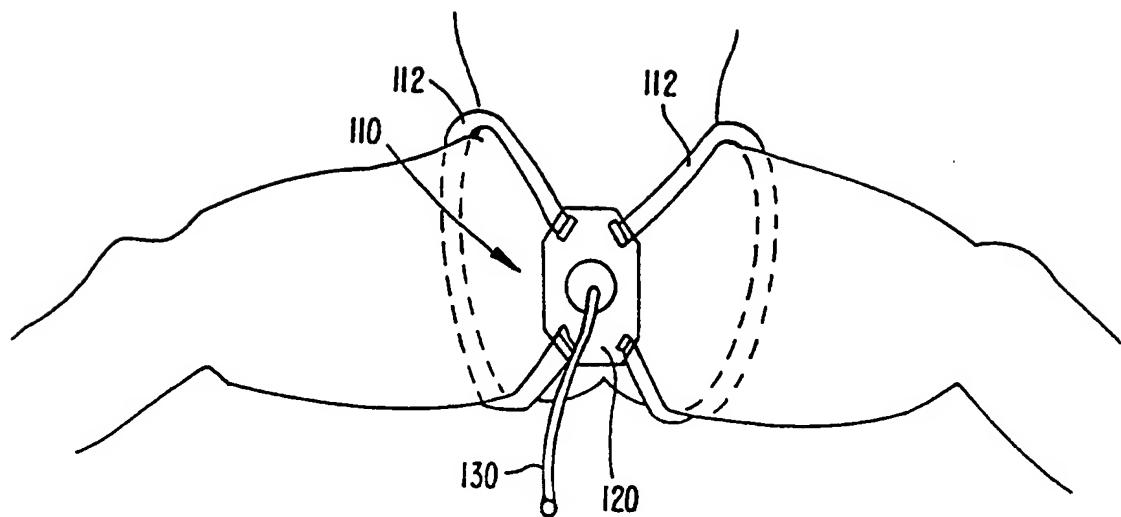


FIG. 8.

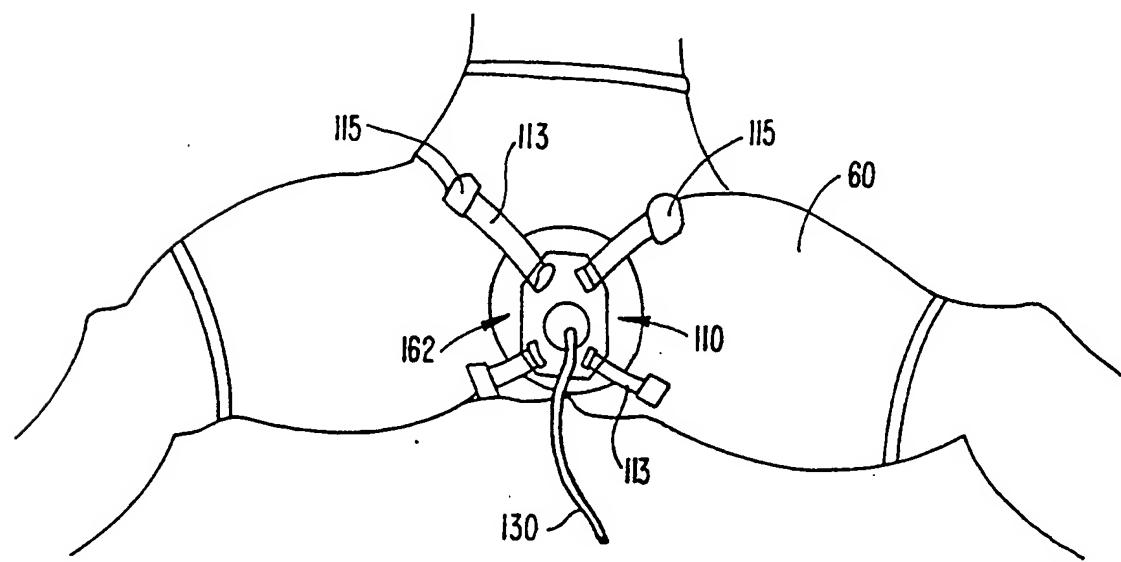


FIG. 9.

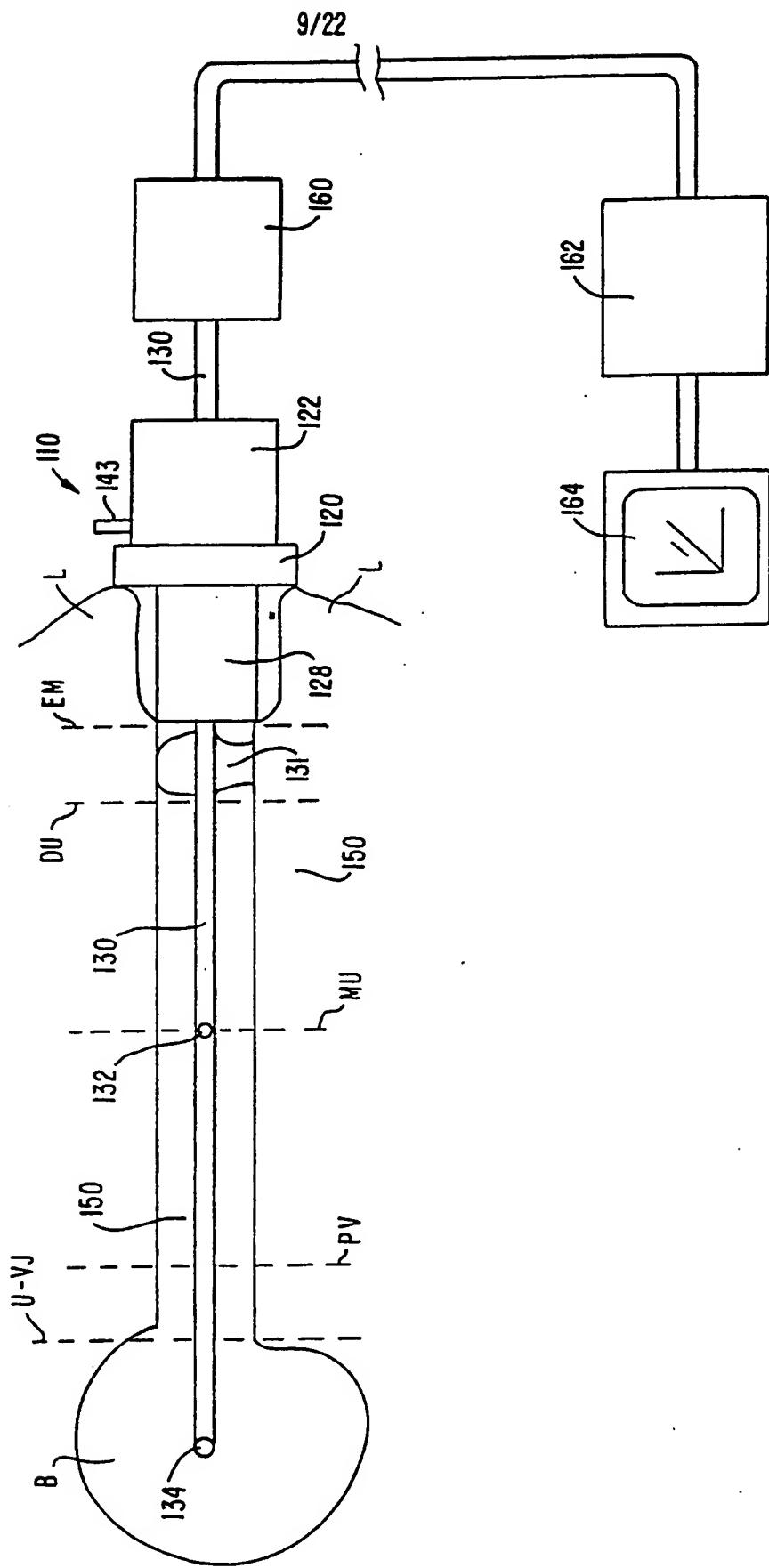


FIG. 10.

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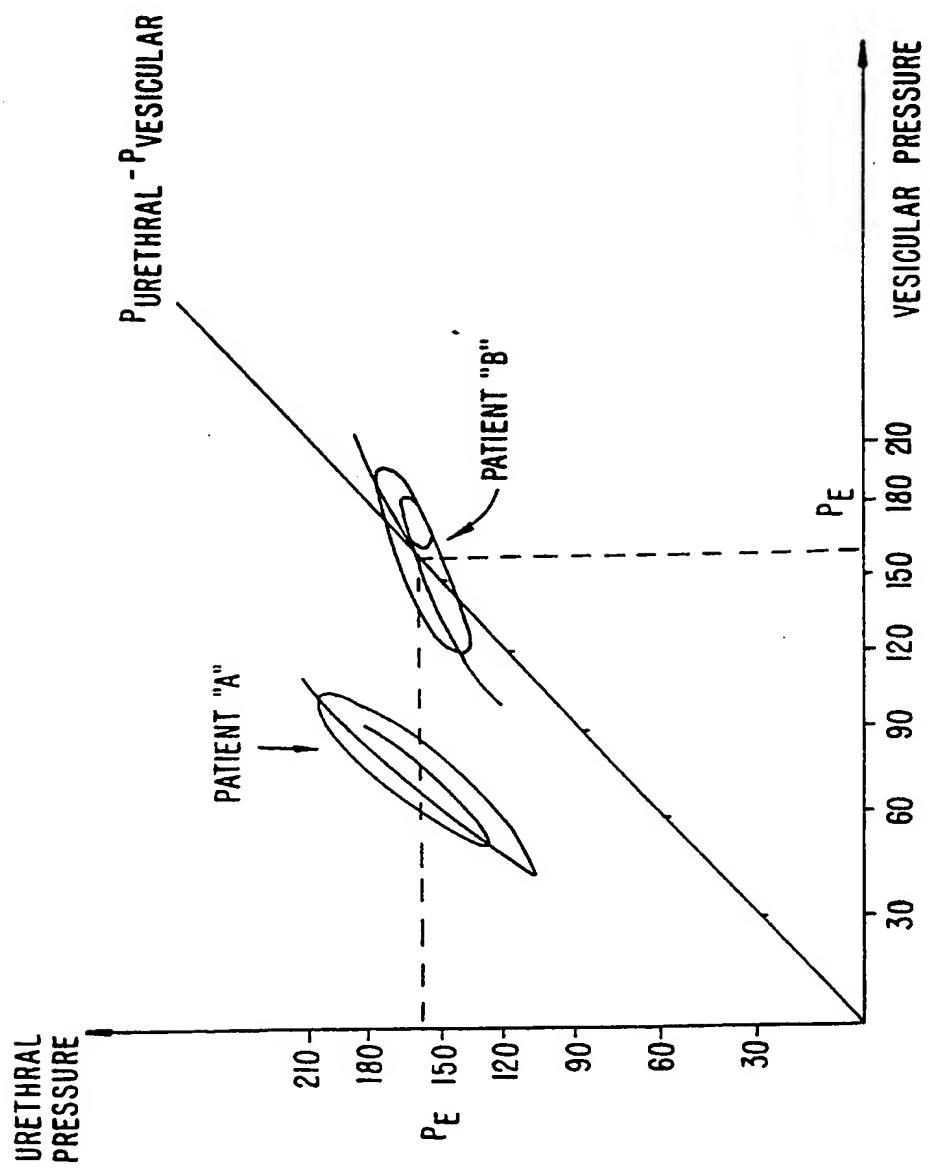


FIG. II.

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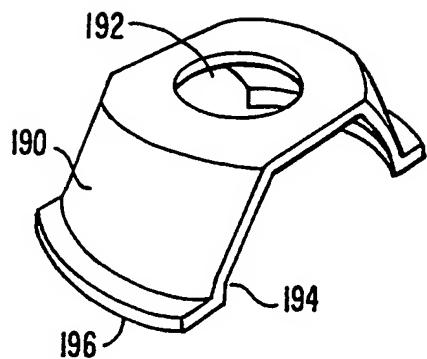


FIG. 14.

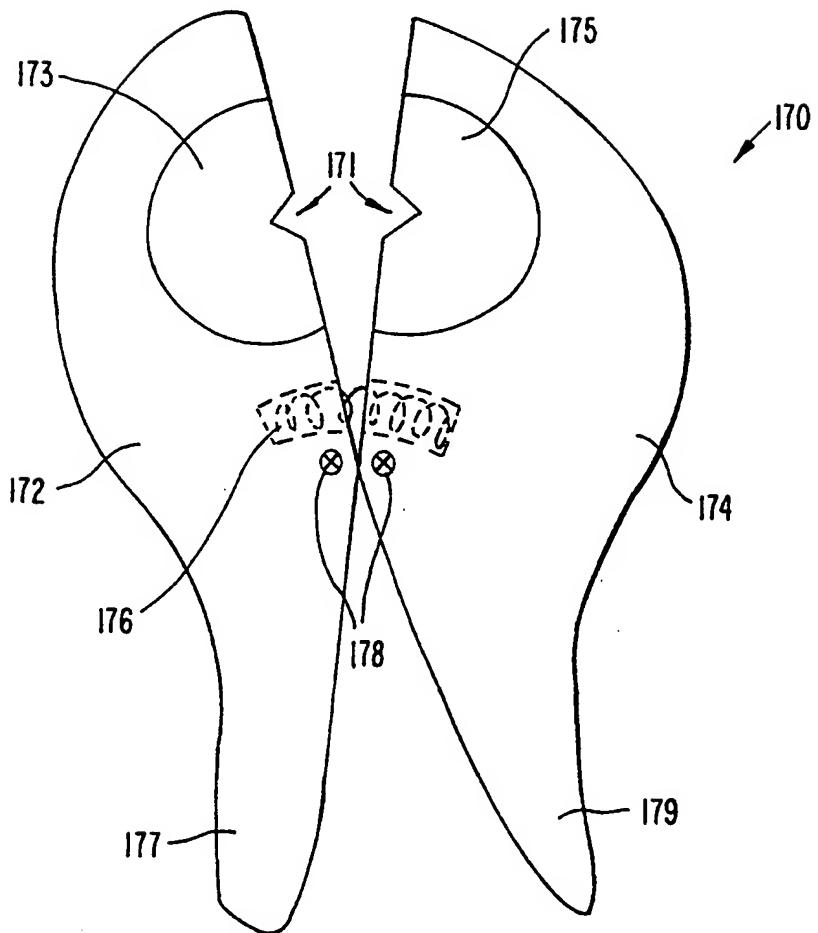


FIG. 12.

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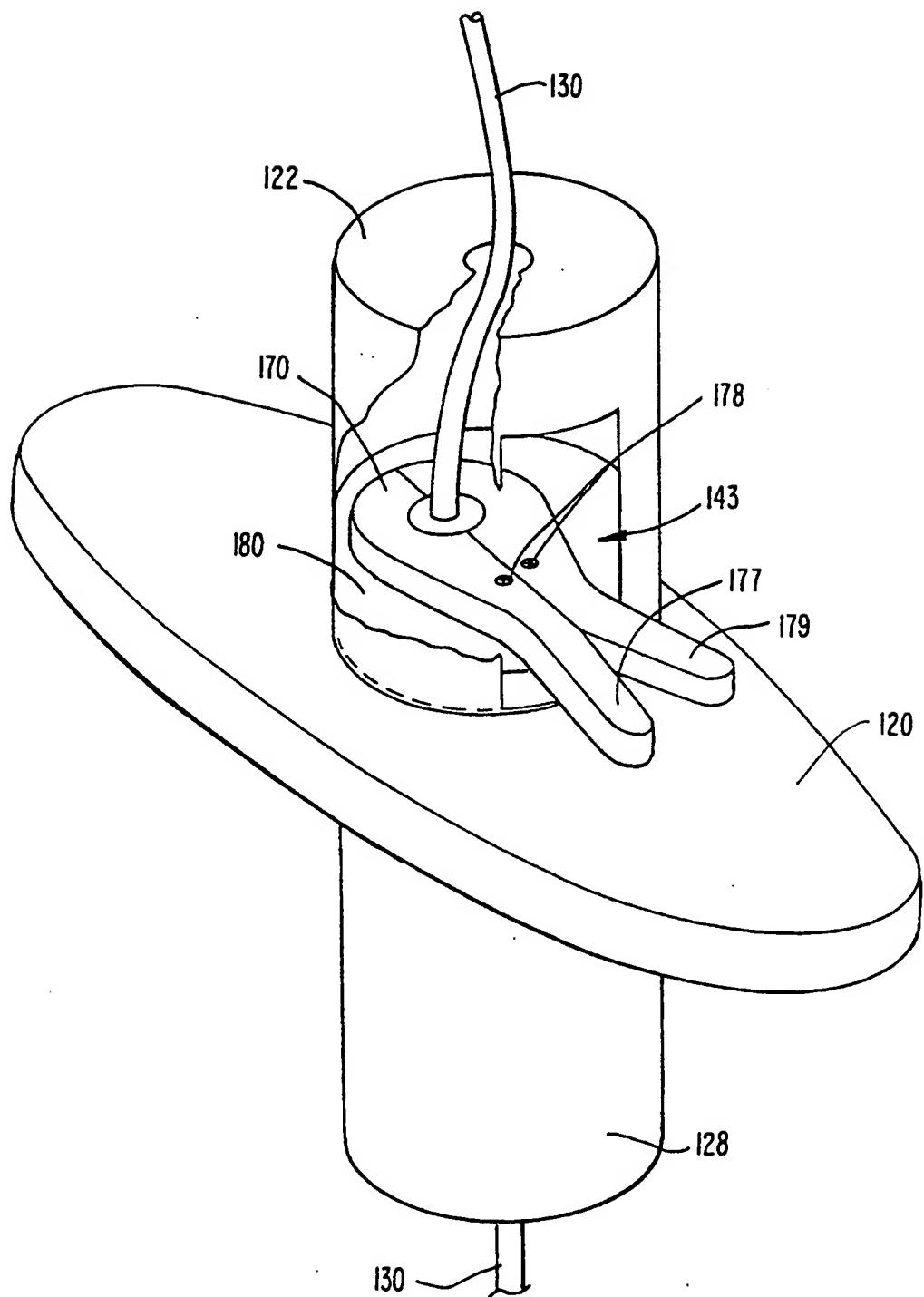
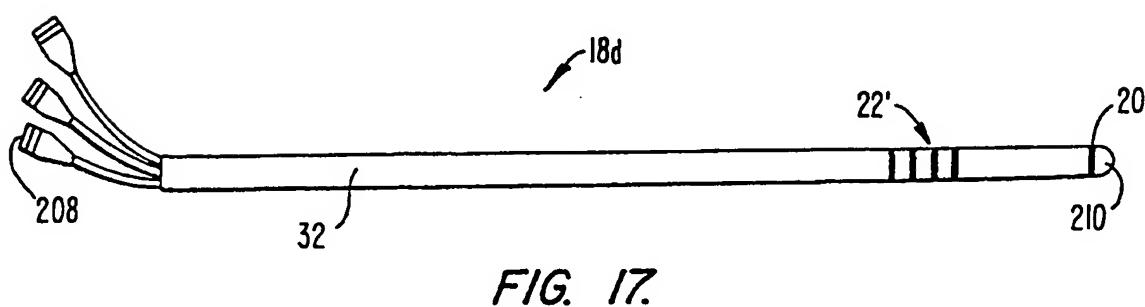
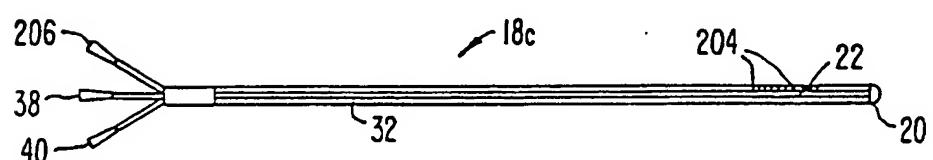
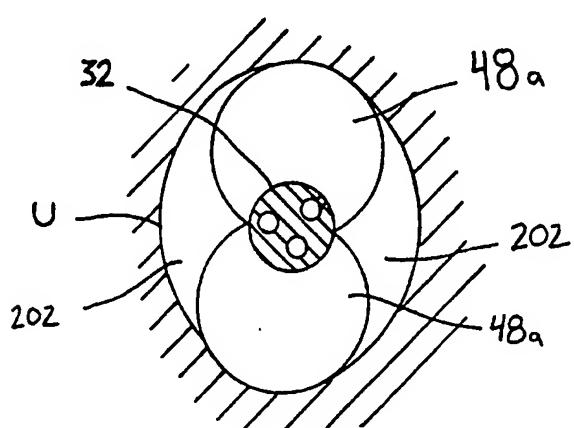
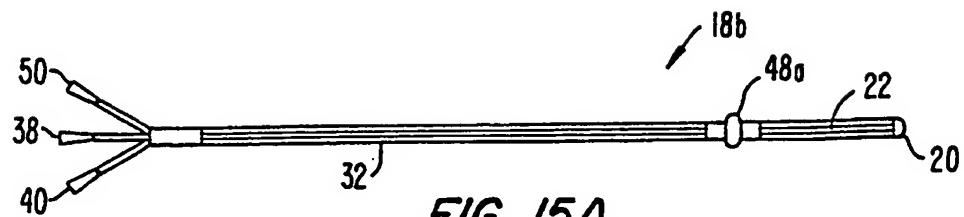


FIG. 13.
SUBSTITUTE SHEET (RULE 26)

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14/22

PATIENT: Example

DATE:

++++++

SURx UPM Ver 1.05

mid three little

TIME:08:20:13

SENSOR S/N=Y321

PU SENS.= 110.6031 PV SENS. 100.1075 PA SENS. 108.7434
ZERO;PU= -2.700271 PV= -17.47311 PA= -9.292039

PV	PU	PA
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24.99999	109.091	2.94E-07
24.46236	108.8209	2.94E-07
24.99999	109.361	2.94E-07
24.46236	109.091	2.94E-07
24.99999	109.091	2.94E-07
24.73118	109.091	2.94E-07
24.73118	108.8209	2.94E-07
24.73118	108.5509	2.94E-07
24.73118	108.8209	2.94E-07
24.73118	108.8209	2.94E-07
24.73118	108.5509	2.94E-07
24.73118	108.5509	2.94E-07
24.73118	108.5509	2.94E-07
24.73118	108.2809	2.94E-07
24.46236	108.0108	2.94E-07
24.73118	108.2809	2.94E-07
24.46236	107.4708	2.94E-07
24.99999	107.7408	2.94E-07
24.73118	107.7408	2.94E-07
24.99999	107.4708	2.94E-07
24.73118	106.9307	2.94E-07
24.99999	107.2008	2.94E-07
24.73118	106.6607	2.94E-07
25.26881	106.6607	2.94E-07
24.73118	106.6607	2.94E-07
24.99999	106.9307	2.94E-07
24.73118	106.1207	2.94E-07
25.26881	106.6607	2.94E-07
24.73118	106.3907	2.94E-07
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FIG. 18.

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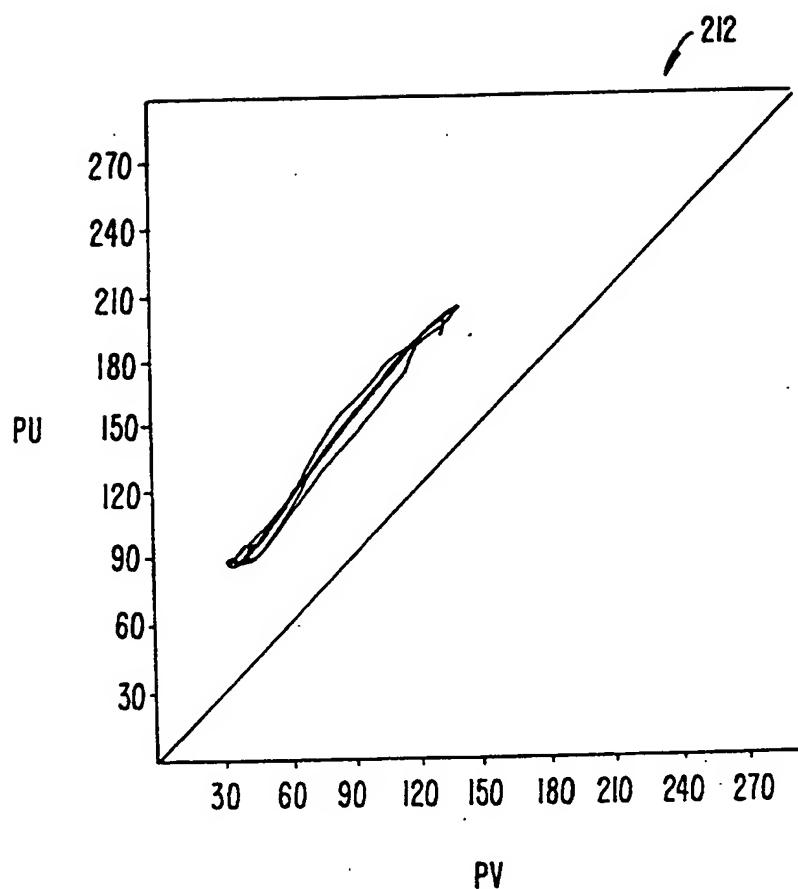


FIG. 19.

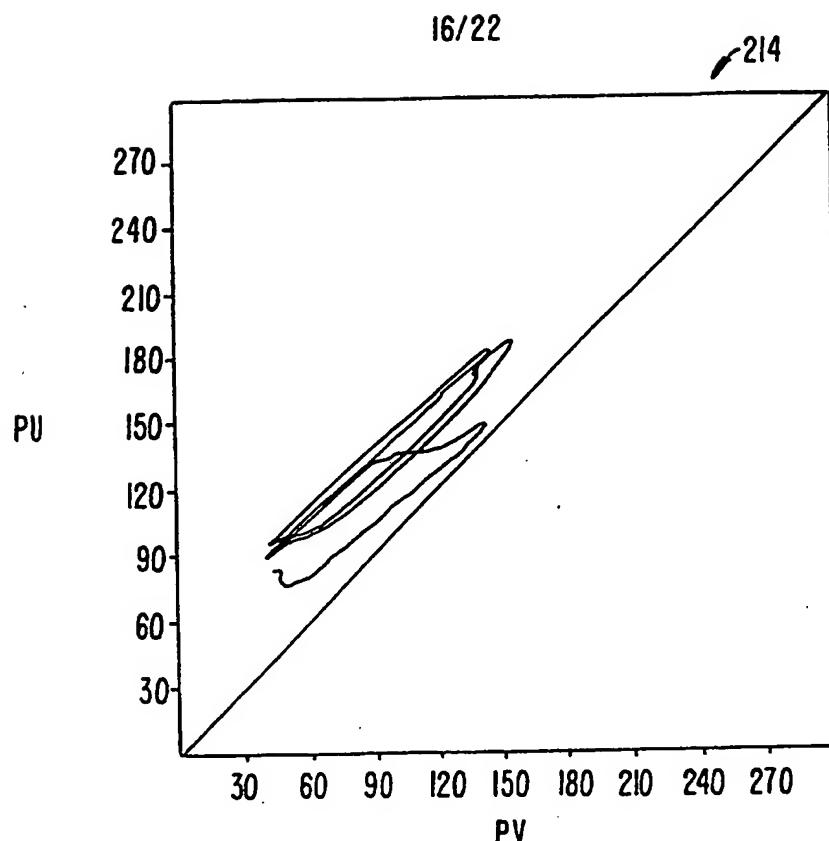


FIG. 20A.

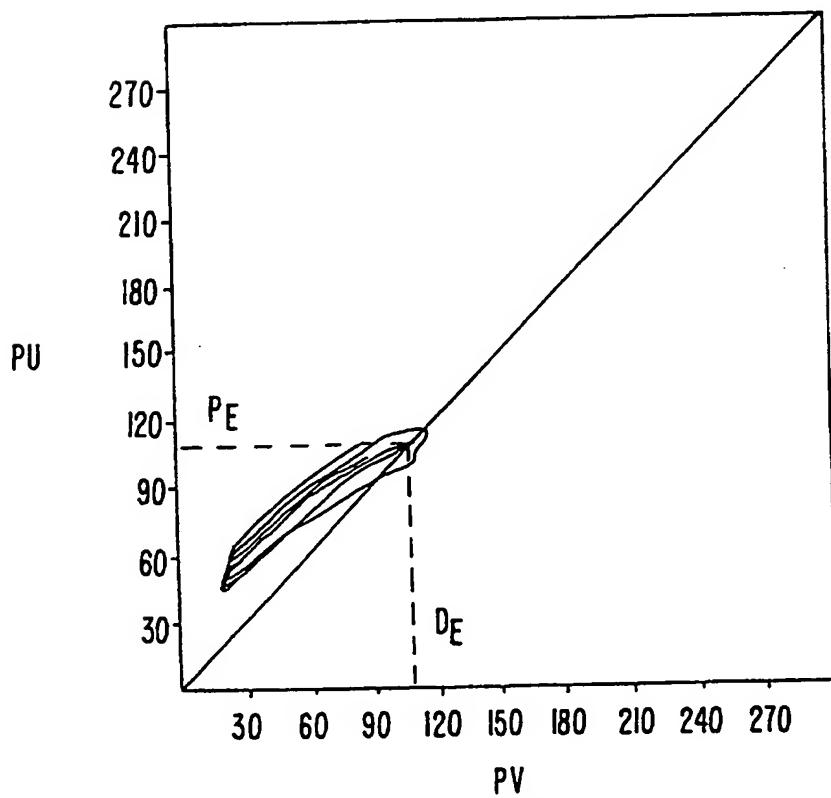


FIG. 20B.

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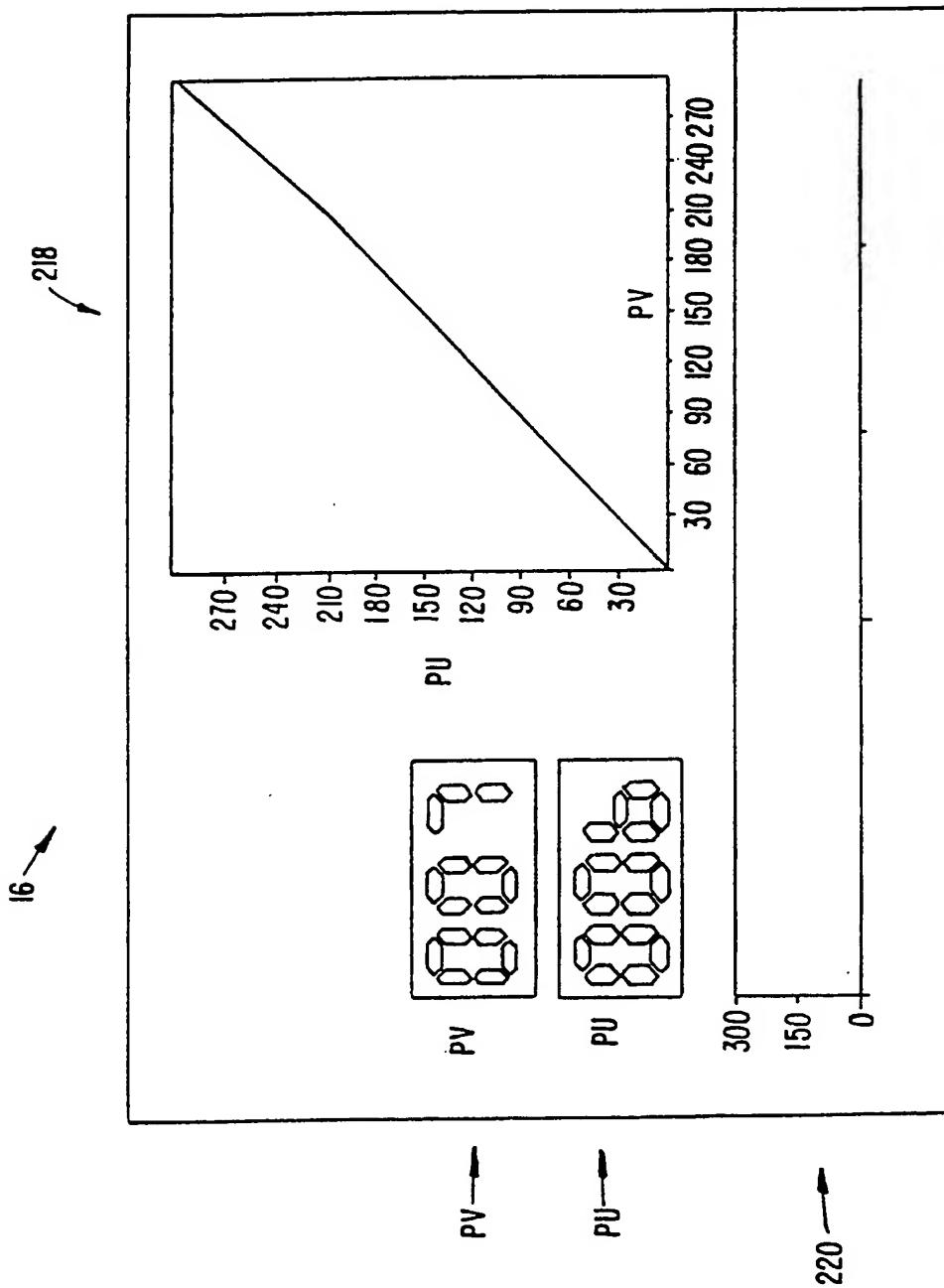


FIG. 21.

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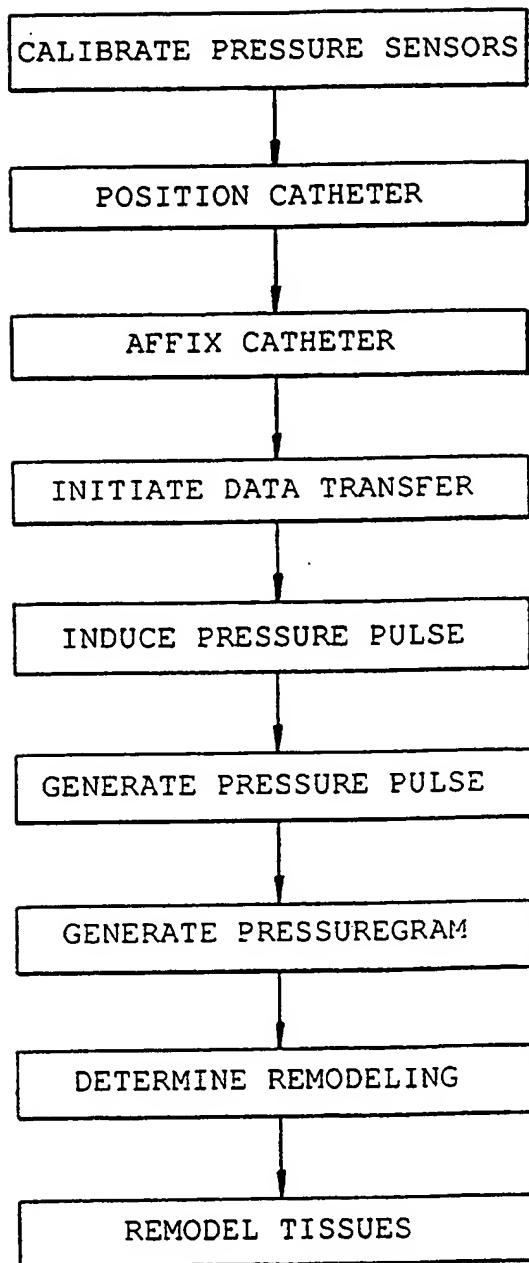
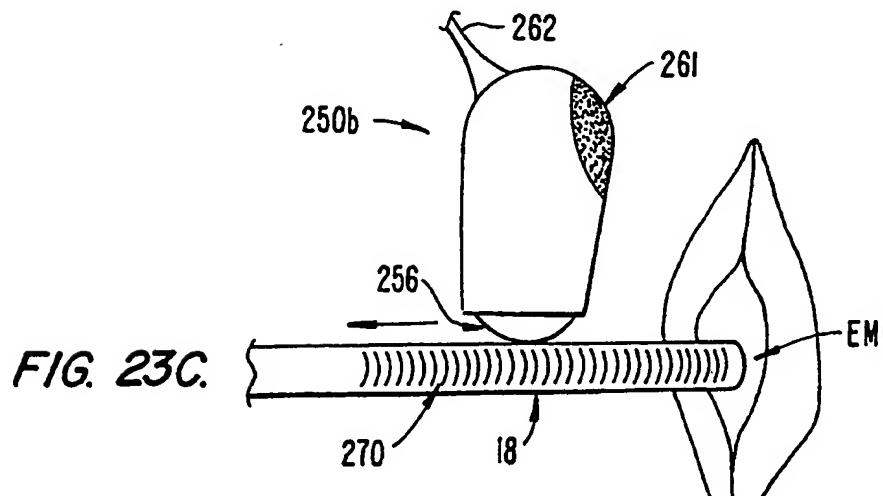
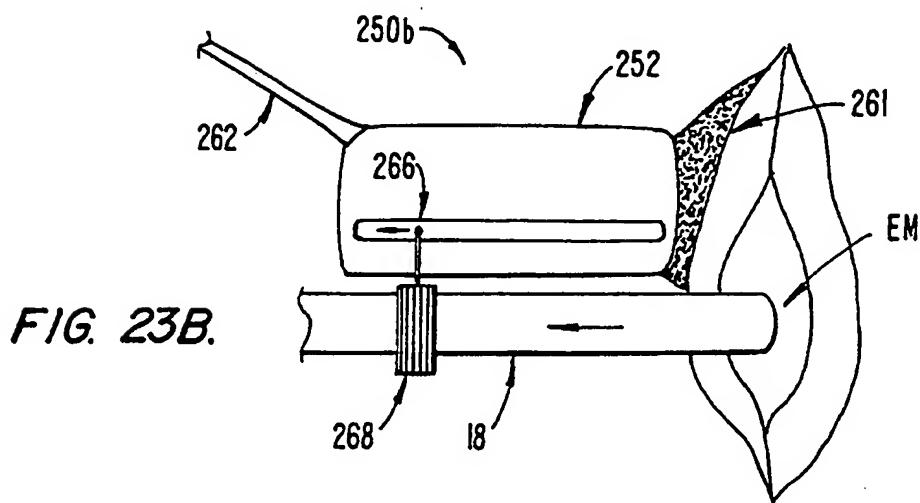
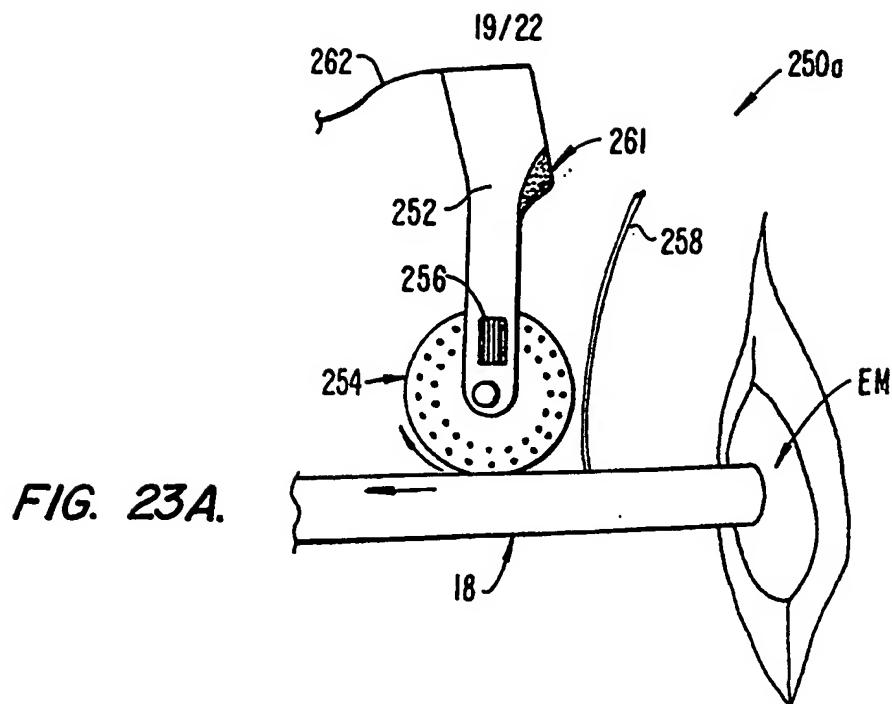


FIG. 22.



SUBSTITUTE SHEET (RULE 26)

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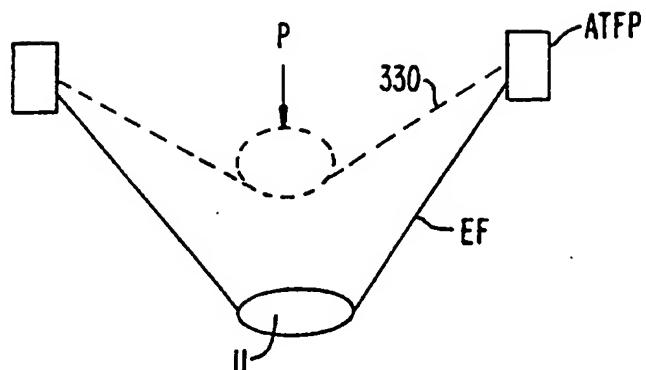


FIG. 24B.

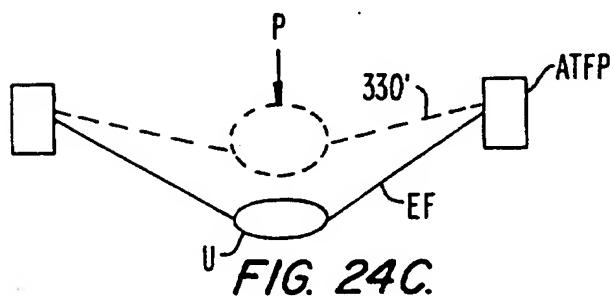


FIG. 24C.

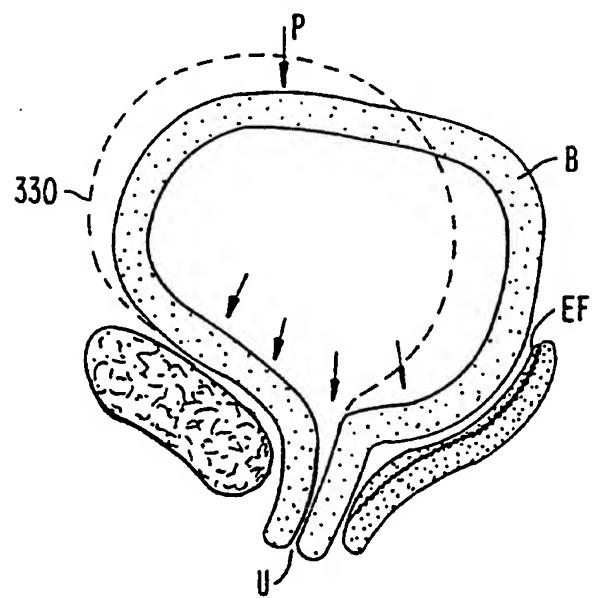


FIG. 24A.

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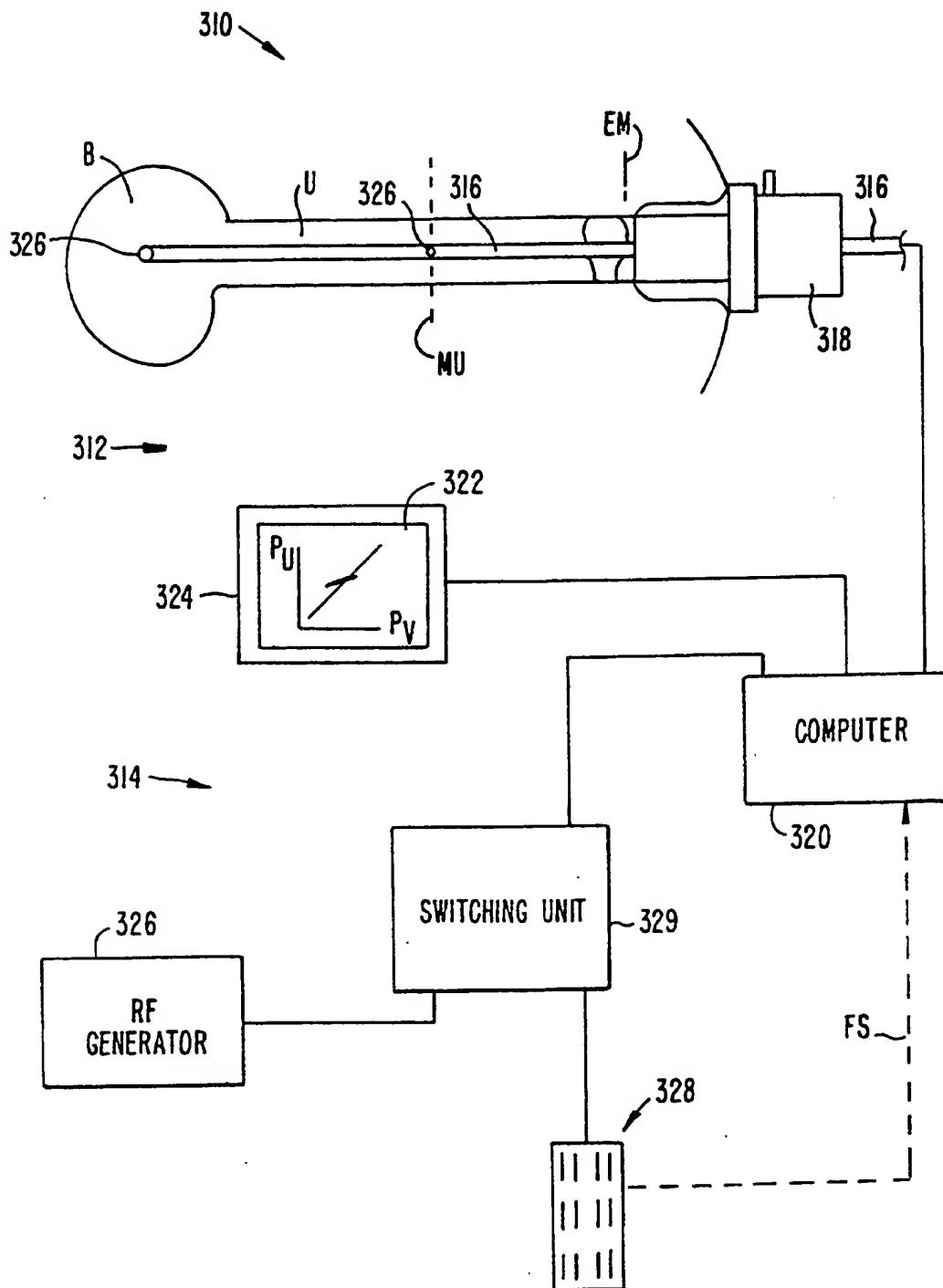


FIG. 25.

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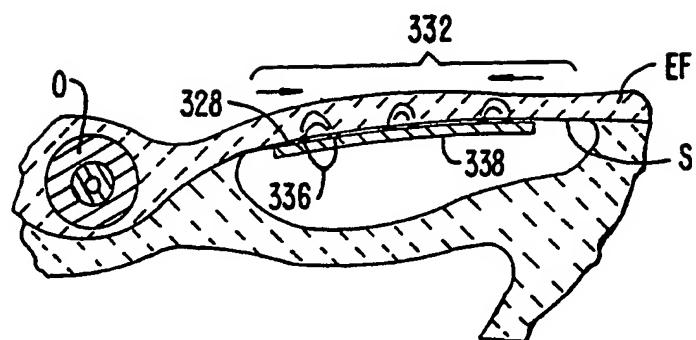


FIG. 26A.

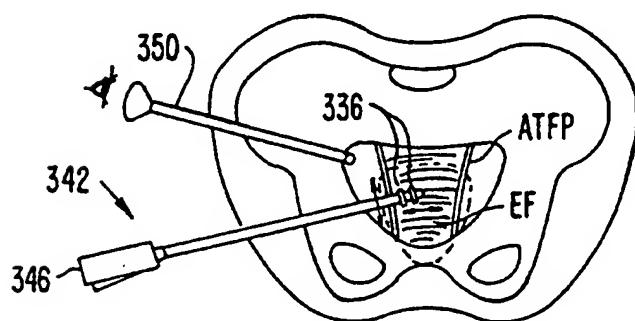


FIG. 26B.

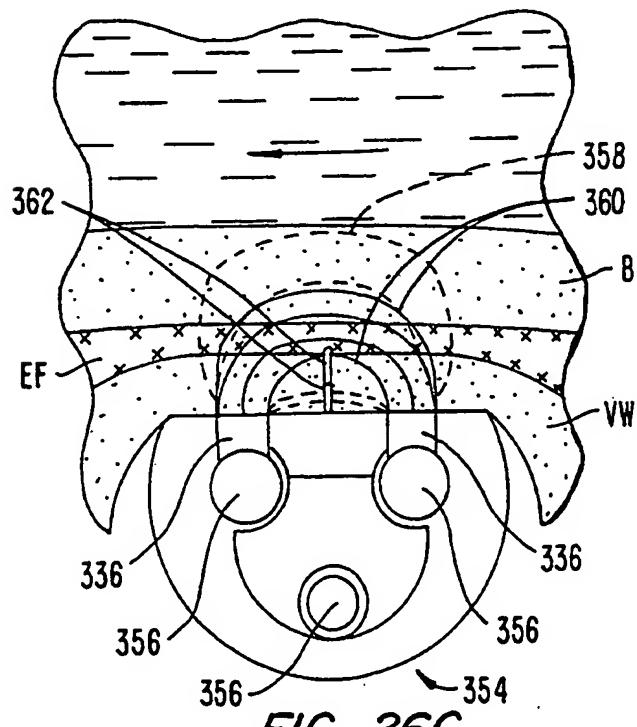


FIG. 26C.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/23827

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 1/00

US CL : 600/462, 486, 561, 588, 591; 604/540

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/462, 486, 588, 561, 591; 604/540

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

Search Terms: SUI, urinary incontinence, bladder, pressure sensor, anchoring means, (computer or processor)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,566,680 A (URION et al.) 22 October 1996, cols. 7-21.	1-15

Further documents are listed in the continuation of Box C. See patent family annex.

- * Special categories of cited documents:
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- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search 28 FEBRUARY 2000	Date of mailing of the international search report 04 APR 2000
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